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Ana Riquelme Francistain, executive director of the MedTech trade group Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos (AMID), details the trade and tax incentives that have favoured nearshoring from the US. Additionally, she outlines the sector's regulatory advances, the important regulatory updates with respect to labelling, good manufacturing practices and surveillance AMID has worked to effect, and explains the complex process of public tenders that can take up to five years.

When considering the requirements for dossiers over a five-year period, what level of robustness is necessary? Are stringent controls and extensive data sets required, or are we operating in a country where pre and post-marketing data are more leniently regulated?

The requirements for dossiers indeed vary significantly. However, it is crucial to recognize that simply having data is not enough; it is about the quality and relevance of that data. Moreover, navigating through various stakeholders involves addressing different priorities. For instance, while security and efficacy may be valued by one entity, cost-effectiveness analysis may be the focus for another. This complexity is further compounded during tenders, where competition often revolves around pricing rather than the uniqueness of the technology and the benefit for the patient. Therefore, achieving success in this landscape requires not only meeting regulatory

standards but also navigating through diverse stakeholder expectations.

Is the Mexican MedTech industry's recent success the result of a clear, decades-long strategy, or has it been more of an opportunistic case-by-case approach to investment?

First of all, Mexico is a crucial market within Latin America, much like Brazil. This is not only due to the size of the market, with 120 million people who may need medical devices at some point in their lives. Statistics indicate that every person in the world will need at least four medical devices during their lifetime. This includes not just surgical devices, but also preventive, diagnostic, and everyday products.

Additionally, Mexico's proximity to the United States presents a significant opportunity for us. This has been advantageous for the past 30 years, starting with the first iteration of the North American Free Trade Agreement (NAFTA), now known as the United States-Mexico-Canada Agreement (USMCA). While the Mexican government currently emphasizes nearshoring, this is not a new concept for us. Many companies have been established along the northern border with the United States for decades due to these trade agreements.

So, to answer your question, our success is a blend of long-term strategic planning and seizing opportunities as they arise, leveraging our geographical advantages and the established trade relationships we have nurtured over the years.

Proximity to the United States seems to have been more advantageous for MedTech than pharma. Why?

The difference indeed stems from a couple of factors. Firstly, there is the proximity to the United States, which is a clear advantage. Secondly, the regulatory environment for medical devices has been evolving over the past 20 years, whereas pharmaceutical regulations have been in place for about 55 years. Initially, the lack of regulation in the medical devices sector presented a significant opportunity for growth. Since 2009 we have been working to develop our own regulations to enhance competitiveness with other countries.

Moreover, Mexico has a skilled labor force well-suited to the medtech industry. Our workforce is capable and adaptable, whether formally educated or not, which is particularly beneficial for the production of medical devices. Many of these devices require manual assembly, and our cultural

aptitude and craftsmanship play a crucial role here. This has allowed us to employ a diverse workforce, including housewives and others, providing them with valuable job opportunities.

That means for many of the companies you represent, there has been a significant effort to skill up individuals, provide training, and make continuous investments. Can you provide any figures on the contribution of these companies to Mexico's economy, particularly in terms of employment and the training of human resources?

The medical devices sector employs around 160,000 people in Mexico, which is more than the pharmaceutical sector. These jobs are typically well-paid, and our companies invest significantly in training and continuous development. For instance, women make up 51 percent of our workforce, a notable figure in manufacturing industries. We train many of them to handcraft complex devices, such as coronary stents, which are then sent to quality control for cleaning and final checks.

Additionally, we are beginning efforts to collaborate with public universities to align educational programs with industry needs. Mexico is known for producing excellent engineers, and many may be eager to join our industry. This collaboration helps ensure a steady supply of skilled labor tailored to our requirements.

Our industry's commitment to diversity and inclusion also sets us apart. We are open to hiring from various backgrounds, and this diversity contributes to our innovation and growth. By fostering an inclusive workplace, we not only enhance our operational capabilities but also provide valuable employment opportunities to a broad segment of the population.

Is there a system of tax breaks or incentives that companies benefit from today to upgrade and maintain their investments, especially for those with multiple factories?

For the past 30 years, one of the keys to our success has been the Maquila program. If you are located near the Mexico-US border, you can operate as a "Maquila." This means you produce medical devices in Mexico specifically for export purposes under the Manufacturing, Maquiladora and Export Services (IMMEX) agreement and your benefit is a tax incentive, which significantly promotes investment in Mexico.

The tax incentive is not limited to the United States, but given our geographical proximity, the majority of exports are indeed to the US. This framework relies heavily on the stable relationship

between the United States and Mexico.

The relationship between the United States and Mexico has seen moments of instability, particularly around trade agreements like NAFTA. How has this affected your members? Are those concerns now behind us?

We have generally experienced stability. In fact, we have a long-standing program, IMMEX, that allows companies to established anywhere in Mexico to manufacture for export and get all the benefits of a free trade zone. This stability has allowed us to attract and maintain investment. For instance, we have companies like Medtronic, Stryker, Becton Dickinson operating along the border, highlighting the program's success.

In our association, AMID, we have 40 factories operated by 12 different members. These companies are continually working to attract more investment. We also have German companies like Siemens actively participating, demonstrating that this programme is not just limited to US products but is attractive to international investors as well.

Let us talk about AMID. Could you elaborate on its vision and your current agenda?

Our vision has always been to improve and promote better access to medical devices for Mexican patients. This has been our goal since the beginning. In early 2020, just before COVID-19, we introduced four key objectives to enhance this access.

The first objective is implementing good regulatory practices. This means we aim to follow the best possible methods, not just in regulation but also in business ethics. The second objective is to help both public and private stakeholders combat the black market. We recognize that introducing our products responsibly is crucial because there is a significant risk of black market activities. The third objective focuses on promoting access through value-based healthcare and efficient procurement practices. Lastly, the fourth objective is to uphold business ethics.

Your objectives are access, cultural alignment, value-based healthcare, accountability, and business ethics. Which area has been the most challenging for the board?

We have spent the most time dealing with regulatory matters. Ensuring that we meet both national and international standards has been a continuous effort. The concept of medical devices has been around for a while, but the specific regulation has evolved significantly. We have made considerable progress. This year and last have been very positive for us. We have worked closely with the Federal Commissioner to review and update our three most important regulations. These include labelling, which we first reviewed in 2009, and then again recently. We also updated our good manufacturing practices regulation, originally from 2012, last year due to various challenges. Additionally, we have been focusing on surveillance.

the Federal Commission for Protection against Health Risks (COFEPRIS) decided to introduce ten regulations for health purposes, and three of these were specifically for medical devices. This prioritization is crucial for us and underscores the importance of our contributions to shaping regulatory frameworks that support innovation and ensure patient safety.

Last year also marked a significant milestone for us as we successfully introduced the concept of medical devices into general law for the first time.

With the trend of US nearshoring amid decoupling from China, do you see potential threats to market homogeneity or intellectual property protection? Are there any issues within the medical device sector related to this?

Almost all the components for medical devices are produced in Mexico, although not all. China remains a significant producer of medical devices, and some components for our members' products do come from China. We are fine with this as long as they meet our quality standards. However, the next phase of nearshoring is to produce the final medical devices

There are several key opportunities for global investors. Firstly, there is a significant need for local production of medical-grade raw materials, such as biopolymers which are currently sourced mainly from Europe. This presents a substantial opportunity for companies to establish production facilities in Mexico. Secondly, there is a crucial need for sterilization services. Currently, many products must be sent to the United States for sterilization before being returned to Mexico, which is costly and inefficient. Establishing sterilization facilities in Mexico would streamline this process and reduce costs. Lastly, secondary packaging is another area with considerable opportunities for investment. By addressing these needs, global players can contribute significantly to the growth and efficiency of the medical device industry in Mexico.

What about the Mexican market? You mentioned earlier that there are 120 million citizens, and we are in a middle to low-income country. How is the market divided between the private and public sectors for your members? What are the key drivers for each of these markets?

The biggest market is, of course, the public sector, which accounts for 80 percent of the products by volume. For example, the Instituto Mexicano del Seguro Social (IMSS) is the largest public health institution in Latin America. The consolidation of the public sector has made it even larger. The remaining 20 percent is the private sector. However, since the pandemic, there has been a shift. Many people have turned to the private sector to manage their health due to the overcrowding in public hospitals. Since 2022, we have been in talks with the Asociación Nacional de Hospitales Privados, the Asociación Mexicana de Instituciones de Seguros, and the Consorcio de Hospitales Mexicanos to improve collaboration and practices.

Innovation is a buzz word in the industry. How up-to-date are the standards in the public sector, and does this include the medical device market?

Innovation is indeed crucial, but access to the public market can be challenging. For public tenders, it takes about five years from the introduction of a product with Cofepris. This involves multiple stages: approval from COFEPRIS, which can take up to two years, followed by evaluations from the Consejo de Salubridad General and various institutional evaluation areas for specific hospitals. This process often takes five years. In contrast, if you receive authorization from COFEPRIS in two years, you can immediately sell in the private sector.

While some resolutions may indeed take longer, we have seen a range of timelines. For instance, we have resolutions that are resolved within six months, while others may extend to two and a half years. So, predictability is a significant concern in our discussions. We need clarity on timelines. If it is two years or three years, we need consistency in those estimates. It is essential because stakeholders rely on these timelines for planning and decision-making.

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regulated?

The requirements for dossiers indeed vary significantly. However, it is crucial to recognize that simply having data is not enough; it is about the quality and relevance of that data. Moreover, navigating through various stakeholders involves addressing different priorities. For instance, while security and efficacy may be valued by one entity, cost-effectiveness analysis may be the focus for another. This complexity is further compounded during tenders, where competition often revolves around pricing rather than the uniqueness of the technology and the benefit for the patient. Therefore, achieving success in this landscape requires not only meeting regulatory standards but also navigating through diverse stakeholder expectations.

Could you elaborate on the philosophy around tenders informing the procurement process? Is it a case of selecting a single provider to ensure market sustainability, or do they opt for multiple providers?

The tender philosophy typically follows a transparent process mandated by law. Public tenders are published, inviting all the suppliers that complies with technical specifications, quality and best price. The selection criteria should involve a combination of technical competency and competitive pricing. Initially, there may have been a tendency to engage multiple producers or distributors for various product types. However, there has been a shift in recent times. Five years ago, the public sector closed the door to distributors but as an industry we have several conversations to explain that quality of the medical devices depends on producers, but good distribution practices depend on distributors. They are an important part of the supply chain. This not only mitigates risks but also fosters healthy competition. However, challenges persist, particularly in ensuring that tender evaluations consider not only price but also factors like best business practices and ethical standards. Establishing and adhering to such standards remains an ongoing endeavor for fostering a fair and efficient tendering process.

What are the key priorities your organization, along with its members, hopes to see addressed in the upcoming years, especially given the outcome of the elections?

As outlined in our position paper, there are several challenging areas we are advocating for with the incoming government. Firstly, ensuring universal access to technology-driven medical devices for all patients, with a strong emphasis on diagnosis and prevention. This includes addressing the

issue of healthcare professionals in the public sector who need more training to utilize available technologies effectively. Secondly, we are advocating for greater accountability within the healthcare system, aligning with the principles of value-based healthcare. Additionally, digitalization is crucial across all public sectors, not just healthcare. These are just a few of the priorities outlined in our position paper, which we are happy to share and discuss further. It is an exciting time for the sector, with ample opportunities for companies looking to enter the Mexican market, and we are committed to playing our part in driving progress and innovation.

Before we conclude, is there anything else you would like to emphasize or add?

There are three crucial points I would like to highlight. Firstly, the importance of business ethics in our industry. We are fully supportive of new regulations aimed at upholding human rights standards in the production of components. This presents an opportunity for us to demonstrate our commitment to ethical practices.

Secondly, it is vital to recognize the distinction between pharmaceuticals and medical devices. Our regulations, procurement methods, and distribution practices are inherently different, and it is essential for governments worldwide to acknowledge and respect these differences.

Lastly, I want to stress the need for regulatory frameworks to adapt to the nature of innovation in medical devices. Unlike pharmaceuticals, which may have longer product cycles, medical devices often require frequent software updates and incremental improvements. Regulatory processes must be agile and responsive to support this iterative innovation cycle.

These are critical considerations that we're actively advocating for with authorities and stakeholders to ensure the continued advancement of the medical device industry.

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