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Rafael Gual, general director of CANIFARMA, the chamber that brings together multinational and local drug manufacturers, details how the organization is currently intensifying its efforts to ensure the pharmaceutical industry as a whole is officially recognized as a strategic Mexican industry by both the Ministries of Health and Economy, while also providing an overview of the main trends and dynamics that are currently impacting the Mexican industry.

When we met with you in 2014, you highlighted that the pharmaceutical industry in Mexico was undergoing a rapid transformation, while offering interesting opportunities to international investors. How has the sector evolved since our last meeting?

Over the last two years, the pharmaceutical industry in Mexico has been rising in importance as a critical sector for Mexico's economy and its population. As a result, CANIFARMA continues to work closely with the Ministry of Economy to ensure our industry is finally and officially recognized by the government as a sector of strategic importance for our country. Besides reaching this official recognition, CANIFARMA's focus revolves around six main pillars. As part of these key priorities, CANIFARMA then concentrates its efforts on attracting more investments to our country, supporting and promoting the export strategy of the entire industry, contributing to the creation of regional clusters of expertise, bolstering research and development activities in the country, and also fostering the development of institutional providers.

The pharmaceutical industry's investments in the country have increased by 90 percent from 2007 to 2013, and these investments continue to increase by seven percent annually. What makes Mexico such an attractive market for the pharmaceutical industry?

First of all, Mexico boasts promising and positive economic and demographic indicators that play a decisive role in convincing potential investors to see Mexico as a key and attractive market. Our country is indeed back to robust economic growth, as the World Bank predicts our GDP will increase by 2.6 percent in 2016, before further accelerating to reach 2.8 percent and 3 percent growth in 2017 and 2018 respectively – strengthening Mexico's position as a key economic driver for the Latin American region. In the meantime, Mexico's population continues to grow at an estimated annual rate of around 1.3 percent adding more than 1.6 million people each year to our 127 million-strong population.

The pharmaceutical industry is also further leveraging the developing recognition of COFEPRIS as a leading regulatory agency from an international standpoint. As a result, Mexico has been consolidating its positioning as a major gateway to other Latin American markets over the last few years. In this regard, local companies and international players implanted in the country increasingly consider Mexico a hub to export to other regional destinations, while our geographical proximity with the United States, the world's most important pharmaceutical market, also contributes to nurture a sound and strong investment flow to our country.

In 2015, the pharmaceutical industry represented around 3.1 percent of the total Manufacturing GDP of the country, whereas in 2009 it was around 5 percent. What can we do to ensure this decreasing trend doesn't continue in the upcoming years?

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This figure simply reflects the fact that other key Mexican sectors, such as automotives, aeronautics, and the IT industry have been growing more rapidly than the pharmaceutical industry. Although the pharmaceutical industry hasn't been able to follow the growth pace of these three other sectors, our industry has however indisputably been thriving over the last few years.

Nevertheless, this figure, among other important rationales, perfectly embodies the necessity to recognize the pharmaceutical industry has one of Mexico's strategic sectors if we want to effectively sustain the continuous growth of our industry and the development of related suppliers. In this regard, this strategic recognition should not only concern the main pharmaceutical companies implanted in the country, but the entire value chain. For the automotive sector, all related suppliers and providers have been included within this strategic designation, and the sector as a whole (including manufacturers and all their suppliers) is now considered as a strategic Mexican industry.

It is noteworthy that our industry has a high impact on the entire value chain, as 161 productive sectors are economically related to the needs of our industry, be it for medicinal or veterinary products or medical devices. Our sector goes beyond pharmaceutical companies and must be considered an entire eco-system comprising a variety of different providers and suppliers – in the same fashion as the automotive sector.

Reaching this governmental recognition will continue to stand as CANIFARMA's utmost priority until it effectively becomes a reality. We are currently liaising with both the Ministry of Economy and the Ministry of Health to confirm as soon as possible this two-fold acknowledgement, and we expect the situation to reach a positive outcome by the second half of 2016.

During our last meeting, you highlighted CANIFARMA's ambition to foster the local production of active ingredients (API); however, 92 percent of the total consumption of API in

Mexico is still imported. How could the development of API manufacturing be further fostered in the country?

Further building and gathering a strong and competitive Mexican API manufacturing remains one of the remaining challenges we are still facing as an industry. We are still looking at identifying the incentives that would effectively trigger the dawn of this important sector, while API represents around 80% of the production cost of pharmaceutical products. As CANIFARMA, we strive to accompany and bolster the development of both domestic and international players in this field. We stridently believe there is a huge opportunity for Mexico to develop a cutting-edge and world-class chemical sector in relation to API production, while manufacturing facilities in competing countries such as China are steadily becoming obsolete and will require important investments to be updated. If we combine the highest quality and manufacturing standards with the historical competitiveness of our manufacturing sector, Mexico then undoubtedly holds the potential to become one of the foremost nations in this field.

In terms of Mexico's manufacturing prowess, the new versions of the NOM 164 and 59 will officially enter into force in August 2016, which will significantly upgrade the Mexican regulatory standards in terms of Good Manufacturing Practices for the pharmaceutical industry. Following the implementation of these two new norms, Mexico also applied to enter the PIC/S system (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme), and COFEPRIS should finally join this organization in the upcoming weeks, highlighting the country's progress to meet the highest international standards. Although a few companies may financially suffer from the investment burden that complying with these new norms could imply, this important regulatory update will however significantly upgrade the manufacturing processes of our industry, and as a consequence- improve the competitiveness of our industry on a mid-term perspective.

Another key topic is the development of clinical research investment in the country, which grew by more than 80 percent between 2007 and 2013. In 2014, you regretted that the industry was not able to conduct clinical research in the IMSS health centers, because the ownership of the results would have been claimed by the institution, even if research was paid by the industry. How has the situation been evolving since then?

Increasing clinical research investments in Mexico is of the utmost importance to CANIFARMA. In February 2016, Mikel Arriola Peñalosa, former Federal Commissioner of COFEPRIS, was appointed general director of IMSS, the Mexican Social Security Institute which covers around 70 million private workers. Since his appointment, fostering the collaboration in terms of clinical research activities between the industry and IMSS is one of the key subjects that we have been discussing. Furthermore, in collaboration with the twelve different administrative branches of IMSS, we have been working over the past year to develop a pilot program that aims at identifying and eliminating the main obstacles that still hinder the crucial development of clinical research activities within IMSS health centers.

In the upcoming months we will release the main findings of this joint study, which should lead to the implementation of more efficient and transparent processes for conducting clinical research activities within the IMSS framework. Considering the recent appointment of Mikel Arriola and the impressive achievements that COFEPRIS has been able to reach under his tenure, we are confident that this period represents a great opportunity to increase the level of clinical research investments reaching Mexico, while our country's potential in this regard remains unfortunately largely untapped.

Bolstering an increased collaboration between the pharmaceutical industry and IMSS with regards to clinical research will also stand as a powerful way to build stronger ties between the private sector and public research centers, while a survey we conducted in 2015 found that 70 percent of clinical

studies in Mexico are still conducted in private research centers. Furthermore, 81 percent of the respondents of our study gauged that approval timelines of public centers' clinical committees were substantially longer than in private research centers, which explains why public centers remain underutilized by the industry. Nevertheless, as soon as all players share the same objective, I am particularly optimistic about the positive development of the situation, and in less than a year, the clinical research landscape in Mexico will be completely different.

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According to a 2014 KPMG study, conducting biotech R&D, clinical trials and product testing is more than 35 percent cheaper in Mexico than in the United States, making the country one of the most attractive in the world for biotech product development. Do you think that these low costs are enough to further attract biotech investment?

Although these low research costs for biotech products indisputably stand as a valuable asset to foster the development of Mexico's biotech sector, the strong cost-containment pressure that still frames our public healthcare system clearly prevents most of these treatments from being available in the main Mexican social security agencies: IMSS, ISSSTE and Seguro Popular. Furthermore, the high cost of many of these biotech treatments also makes them out of reach of most Mexican patients that could access them in the private sector. As a result, the development of Mexico's biotech industry will remain largely dependent on the potential improvement of commercial opportunities available to these products in our country.

Nevertheless, this structural impediment doesn't prevent the development of emerging and promising biotech clusters, such as the BioCluster de Occidente in Guadalajara, which already gathers together several research institutions and more than 35 multinational and domestic biotech pharmaceutical companies, or the BioCluster of Nueva Leon.

The government has recently taken some important steps to address the fragmentation of the national Healthcare system and improve the exchange of services among different healthcare institutions. What could be the impact of this universalization of medical services on the pharmaceutical industry?

Fundamentally, these recent reforms will not change the nature of the Mexican market, although from a long-term perspective the implementation of a true universal healthcare system could of course increase the access of Mexican patients to innovative treatments.

Another recent move has been the implementation of consolidated and annual purchasing bids among the different social security institutions. We remain relatively skeptical about these new tenders, which are so large that a single company could not win them, leading pharmaceutical companies to increasingly resort to distributors to meet the government's demand. Another of these government bids is set to be announced by the end of 2016, and we hope that CANIFARMA will be involved in the design of this new tender.

What would be your final message to the executives of companies planning to invest in Mexico?

First of all, be it from an economic or demographic standpoint, Mexico still boasts an excellent and stable macro-economic environment that should draw the attention of any potential investor, while the attractiveness of our pharmaceutical market is further heightened by the quality of our intellectual property regulatory framework. Finally, investing in Mexico allows pharmaceutical companies to both leverage the international regulatory recognition of COFEPRIS and our strategic geographical positioning to fully benefit from the appealing business opportunities that continue to arise all over Latin America.

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