

CANIFARMA â?? Rafael Gual, Executive Director â?? Mexico



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The executive director of the board bringing together multinational and local drug manufacturers talks about the chamberâ??s goal to position the pharmaceutical industry as the most important manufacturing sector in Mexico, how the chamber is working with the government and its membership to reach this goal and which new dynamics are redefining the industry.

One of CANIFARMAâ??s strategic objectives by 2020 is to position the pharmaceutical industry as one of the key manufacturing sectors in Mexico. What is the Chamber doing to reach this goal?

We have been working on a development program for the pharmaceutical industry. We started it with the transition team and made the relevant adjustments once the new government took office in December 2012. The objective is to make sure the pharmaceutical industry represents 20 percent of the Gross Manufacturing Product of the chemical sector in Mexico by 2018. Today itâ??s 17 percent. Yet, besides the numeric objective, what is important is that we are closely working together with the government to ensure the pharmaceutical sector is recognized as an increasingly important player in the economic development of the country.

During the 2013 edition of the CANIFARMA convention the minister of health, Dr. Mercedes Juan and the vice minister for industry and trade, Dr. Jes s Ignacio Navarro, appointed the pharmaceutical industry as a strategic sector for the Mexican economy. This helped us accelerate the development program and open doors for drug manufacturers to access financial support and stimulus from different government institutions such as the bank and export credit agency BANCOMEXT, the international trade agency Pro Mexico, the development bank Nacional Financiera (NAFIN), the National Institute for Entrepreneurship (INADEM) and the National Council for Science and Technology (CONACYT). This collaboration has allowed us to give drug makers a large number of opportunities, which companies are already taking into consideration and will open

more alternatives in the future.

A further objective of CANIFARMA was to help COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) recognized by the PAHO (Pan American Health Organization), which was accomplished in 2012. What does this recognition mean for the sector?

This recognition represents a very valuable asset for Mexico and it opens up the scope of opportunities for the Mexican pharmaceutical industry. It implies an increased transparency and standardization in the documentation of all manufacturing processes – something like an ISO certification – which translates into a more solid regulatory framework, and in turn makes investment, import and registration of new products much easier. National manufacturers and new companies in Mexico are probably the ones who will profit mostly from this recognition, as it opens to them the access to international markets especially in Latin America. Given the high levels of competition present in Mexico, it offers companies interesting opportunities for growth.

The Chamber also wants to position Mexico as a leader in clinical research. What are the current challenges faced by drug manufacturers in the country to conduct clinical trials?

Taking into consideration the high percentage of Mexican population in the US and the proximity to the most important drug market worldwide, our country has a huge potential as a hub for clinical trials for the whole region. However, Mexico still lags behind in terms of clinical research. The situation has improved over the past few years, but not at the speed we would have liked it to. One of the obstacles we see is the time for approval of clinical trials by hospitals ethical committees and by COFEPRIS. Approval times have improved in comparison to the past, but a lot needs to be done yet. We have already a list of institutions for different specialties, which can work as third parties to authorize clinical trials in the country, but the process is still very slow. A further hindrance so far has been not being able to conduct research at IMSS, the largest health institution in the country, because the ownership of the results would have been claimed by the institution, even if research was paid by the industry. We hope we can overcome these challenges in the near future to make sure the country can take advantage of this trend.

One of the key priorities of the current Ministry of Health is to move Mexico towards a universal National Healthcare System. What do you think will be the main obstacle to make it become reality?

It is a great challenge. The main obstacle I see is the standardization of all services provided by the different institutions. Currently the list of drugs and treatment covered by the three most important public healthcare institutions, IMSS, ISSSTE and Seguro Popular, is very different. Several treatments covered by the ISSSTE, for example, are not so by IMSS or Seguro Popular.

The Ministry of Health has also been aggressively pushing the use of generics, which today represent 85% of the market in terms of volume. How did this change the industry?

In the public sector the impact has not been significant, because generics have always had a high market share and public institutions will continue to purchase innovative drugs for those high-specialty treatments which require them. The recent consolidation of the procurement process of public institutions may have driven down prices, but has not changed the market in terms of units. Yet, in the private market the share of generics soared, also due to the common malpractice of –prescription switching– at pharmacies: a patient comes with a prescription of a specific drug and the pharmacy physician changes it with a house-branded generic product, even if this is forbidden. Sometimes I even fear that they may change medical treatment.

What do you think about the rising trend of pharmacies offering medical consultation at the point-of-sale (POS)?

The trend is here to stay, it is a necessary evil. It definitely changed the rules of the game in the past couple of years, but will not change it that much anymore. It is relieving government institutions from some pressure, it's filling a gap, but we must remember a medical consultation at a POS is far from being equivalent to one at a medical institution. At pharmacies physicians do not create a clinical record and hygiene conditions are questionable. At the beginning of 2014, COFEPRIS hardened the regulatory framework and established minimum hygiene requirements for this kind of practice, but it's difficult to monitor all the POS regularly to make sure they comply with the law. As it is often the case in Latin America, the law says one thing, but what happens in reality is different. At CANIFARMA we believe the regulation of this practice must be increasingly tightened in the future.

In 2012 CANIFARMA completed its first census of the industry. How did this initiative help you better understand the sector?

Indeed we did have information about the industry but somehow it was not backed up by "hard data". The census helped us draw a better picture of the sector to help the government authorities better understand the strategic importance of the pharmaceutical industry for the Mexican economy and convince them of including it in the country National Development Program. It gave us an endorsement we did not have before. We are currently finishing the second edition, which will be called "statistic compendium" and will be published in October 2014.

What are CANIFARMA's main priorities for the next five years?

The main role of CANIFARMA is to impulse the growth of the pharmaceutical sector and make sure the current opportunities become reality in the future "and it's happening. We presented the success stories of several companies in their relationship with the actors mentioned above in our last convention and participants realized growth is feasible. We must be very proactive in helping companies take advantage of the support and tools the government provides. My personal project is to make sure that this happens and transform the pharmaceutical in the most important manufacturing industry in Mexico. Actually, the supports we are facilitating are not only for drug manufacturers, but also for suppliers "and it's a huge opportunity. Last but not least, we want to develop the local production of active ingredients: several drug manufacturers used to have this segment, but do not anymore because of the price war the trade agreements has caused. We firmly believe it's a sector which can be recovered especially in an environment where quality is important and justifies a higher price. The pharmaceutical industry in Mexico is undergoing a rapid transformation, but has been traditionally stable, offering interesting opportunities to international investors.

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