Rafael Gual Cosío – Director General, CANIFARMA, Mexico (Feb 2020)



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Rafael Gual Cosío, director general of the Cámara Nacional de la Industria Farmacéutica (CANIFARMA), the umbrella industry association for the healthcare sector in Mexico, shares his perspectives on the complex situation in the Mexican healthcare landscape today; the importance of positive and open working relationships between the public and private sectors; and the great opportunities in Mexico that can be capitalized on in the right policy environment.

Rafael, as director general of Cámara Nacional de la Industria Farmacéutica (CANIFARMA) and having been part of the Mexican pharmaceutical industry for nearly four decades, could you please share your insights on the ongoing reforms under the current administration?

We are facing a very complex situation. Over the past year, many changes have been made that have transformed the healthcare system in Mexico and unfortunately, the result today is a tremendous amount of uncertainty in the sector. We are talking about policies like the centralization of the procurement processes of medicines and medical supplies for the entire public sector, the replacement of *Seguro Popular* with what is now called the Instituto de Salud para el Bienestar (INSABI), the provision that allows for the importation of medicines unapproved by COFEPRIS from overseas manufacturers, and so on.

With the public procurement processes, there was a complete change in the way that the government wanted the system to be organized but many of the parameters were unrealistic. For instance, the reference prices were taken from the prequalified product list of the World Health Organization, with maximum retail prices set lower than the lowest available prices in Mexico, which are completely unrealistic for companies in Mexico. Therefore, nearly 70 percent of the tenders had no bids from the industry. You can imagine that this result is untenable. At that time, the 2019 full-year supply contracts for the public sector were still in effect, so the rest of 2019 was fine in terms of medicines and medical supplies but the moment we entered 2020, the shortages in medicines started. The public healthcare system is now extremely chaotic.

Over the past two months, we have been trying to work closely with the government to resolve this urgent issue. Two weeks ago, we sat down with the main actors in the public healthcare sector – including the Secretary of the Interior, the Ministry of Health, , the Senior Official from the Ministry of Finance that is now responsible for the public procurement of medicines, as well as the heads of the different public healthcare systems in Mexico (IMSS, ISSSTE and INSABI) – to discuss what should be done moving forward.

I want to especially highlight the fact that despite being invited to this meeting at rather short notice, CANIFARMA urged our members to attend and around 130 of them did so. They were asked to and subsequently did provide their inventories for the medicines in short supply, and we submitted new quotations and proposals for their supply. However, two weeks after the meeting, we still have not received feedback or any orders on these proposals.

In response to the shortage of medicines, the government announced an emergency bill allowing for the importation of medicines from overseas manufacturers without the need to receive regulatory approval from COFEPRIS. I am sorry to say that this reflects a lack of understanding about the way the pharma industry works globally! There are issues of safety, compliance, pharmacovigilance, manufacturing timelines and logistics, just to name a few. It is not feasible to expect that pharma manufacturers can supply millions of units of products at such short notice.

I want to note that during the meeting, CANIFARMA also stressed the importance of starting negotiations for the centralized procurement process for the year 2021 as soon as possible. We need to resolve the supply issue in 2020 but we must also avoid repeating the same mistakes for 2021. We need to undertake new market studies to assess the needs of the public healthcare sector and understand how to respond accordingly.

You also mention the creation of INSABI. How does the industry view this at the moment?

There is a lot of uncertainty regarding the role of INSABI. Great promises have been made but the problem lies in the implementation. So far, it has replaced the previous public system of *Seguro Popular*, which we believe was functioning acceptably well, and today under INSABI, it is not clear what the rules of engagement are regarding the role of the state governments in healthcare provision for their citizens.

Previously, the state governments were in charge of providing health services to their own populations and *Seguro Popular* was the federal institution financing the states' healthcare expenditures. Presently, the federal government has centralized the administration of all healthcare services but the hospitals, the personnel and all the related operations are still those of the states! Therefore, the role of the states is still unclear. In addition to that, the financial question is also unsettled because INSABI is supposed to provide universal coverage but very unfortunately, we do not have enough funds within the system to support free healthcare for all Mexicans.

This is a matter that needs to be resolved between the state governments and the federal entity but at the moment, it is causing a lot of uncertainty within the industry as well.

How open would you say the current administration is to dialogue and collaboration with the industry?

Unfortunately, it has to be said that within the public sector, there is a general lack of information and understanding about how the pharma and medtech industries work. There are some issues of prejudice and misinformation, which have made it difficult for productive dialogues to take place.

We are seeing this across many different government institutions including the Ministry of Health as well as COFEPRIS. For COFEPRIS especially, we are seeing a break in the traditionally positive relationship of open collaboration between the regulatory and the industry.

At the same time, CANIFARMA is advocating for our members to continue to support any efforts from the government. We currently have 186 members across pharmaceuticals and medical technology. We are advocating for new bridges to be built between the public and private sectors. But many of our members are understandably very nervous about the current situation because they lack certainty across all aspects of the public healthcare system in Mexico. Regrettably, I have to say that in a few cases, planned investments into Mexico have been placed on hold until the

situation stabilizes.

I have been in the industry in Mexico for 39 years. This is the toughest moment of my career in four decades! Nevertheless, I am optimistic that under the new senior official of the Ministry of Finance, things will improve gradually. We look forward to establishing productive and transparent processes.

In spite of the current challenges, do you have a final message for our international audience?

What I want to emphasize is that Mexico has truly great opportunities, some of which we can capture in the short term – such as clinical research – and some of which we could capitalize on in the middle to long term. But it also depends on the overall environment and we really need support from the government in terms of the right policies.

In Mexico, CANIFARMA and our members have strong alliances with international and regional associations and institutions. For instance, in Mexico, we work closely with the OECD Mexico Center to promote public health initiatives, and through our member association, AMIIF, we also work with IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), which is a respected body that represents research-based pharmaceutical companies and associations globally. We also have the Consejo de Ética y Transparencia de la Industria Farmacéutica (CETIFARMA), which is the body for ethics and compliance within the entire Mexican healthcare industry, both international and national, and they are a member of IFPMA as well. These international linkages are very positive for the development of the pharmaceutical and medical technology sectors in Mexico.

Finally, I must highlight the silver lining: the challenges we are facing now, while difficult, have brought the entire industry together. Presently, the different associations and industry stakeholders are all working together towards the same goal to promote the health and welfare of Mexican society.

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