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The director of Mexican pharmaceutical industry association CANIFARMA, Rafael Gual Cosío, speaks out about the current contradictions plaguing Mexico's pharma sector. Gual Cosío highlights the fact that market growth and revenue increases are being seen despite regulatory backlog and medicine shortages due to inefficient handling of the public system. He also argues that the reorganisation of Mexico's public health insurance system, Seguro Popular, was hindered by a lack of planning and that the country's pandemic response was "terrible," while remaining optimistic about the future.

To begin, can you highlight some of the main changes in the Mexican pharma market over the last three to four years?

To give a quick example, we have seen important changes on the regulatory side, which have resulted in delays in the approval procedures. I would say the first two years of the current government - led by President Andrés Manuel Lopez Obrador - were complicated, with little to no dialogue. While it remains difficult, some communication did start at some point, although progress has been slow. One area where we have observed improvement is the approval of new molecules, which was halted for two and a half years. Another important subject that jeopardises the industry's operations, is the inefficient acquisition and distribution of medicines for the public

healthcare system.

There is a huge backlog in product authorisation for all categories, new molecules and generics, including modifications of sanitary registrations that were necessary because of the disruption of global supply chains that forced producers to change suppliers of APIs. There are around 6,000 authorisations pending from COFEPRIS (Federal Commission for the Protection against Sanitary Risk). It is noteworthy that COFEPRIS regulates not only medicines – although the pharmaceutical industry might be the agency’s largest client – it controls 12 percent of Mexico’s gross domestic product (GDP). This speaks to the magnitude of the regulator’s responsibility.

Can you walk us through the structure of Mexico’s public healthcare system and the changes made by the current government?

The three most important healthcare providers used to be IMSS (Mexican Institute of Social Security) which provides health coverage for employees of the private sector, ISSSTE (Institute for Social Security and Services for State Workers) which covers public sector employees, and the *Seguro Popular* that would cover those that do not qualify for the other two due to their employment status.

This has changed dramatically. Replacing the *Seguro Popular*, the government created the INSABI (Institute of Health for Welfare) which from the outset did not have a clear structure nor clear operational procedures, and it modified the way to deliver healthcare. The *Seguro Popular*, managed by the federal government, used to allocate funds to the states, which in turn delivered healthcare, but now the INSABI centralized the acquisition and distribution of medicines to the states. Currently, the INSABI has delivered less than two-thirds of the medicines it should have distributed, which has resulted in widespread shortages.

What changes is CANIFARMA proposing on behalf of its members?

As an association, operating as the official communication channel with the government as per the law, we are working with COFEPRIS to find solutions to the backlog. Companies themselves have practically no interaction with the agency since they are represented by CANIFARMA, as well as by the associations they also form part of in many cases. Among others, we are stressing the health risks to the population in relation to the delay in authorization procedures and the backlog generated by it. We are working towards establishing specialised channels for these administrative

procedures, seeking the use of *affirmativa ficta* – which occurs when the lack of response from the authority gives rise to an affirmative response to the petition after a set period of time.

How is this impacting the normal operations of pharmaceutical companies and their portfolios?

Companies are trying to cope with this new reality and continue to seek to cooperate with authorities. The Mexican pharmaceutical market, specifically the private market, has grown more in these last few years than it had in the previous decade, over 12 percent. This is due to the fact that the medicine shortages in the public system have forced people to seek products and in some cases services in the private system. The industry has performed quite well despite the challenges related to regulatory procedures.

The public market has been seriously affected by the system's lack of planning. Such a complex system needs careful and timely planning, and the lack of it means fewer medicines acquired at higher prices. There are no public tenders in the traditional sense, so companies are taking risks by producing certain medicines without a clear demand on the other side.

The government is paying more than before, too, because producers had partnerships with distributors that included distribution in their agreements. The traditionally established distributors that had built their infrastructure for decades were banned by the government, and recently created and therefore, smaller distributors are being selected, many of which do not have the necessary capabilities and infrastructure.

What you describe gives the impression that patients are the ones carrying the financial burden, paying more for medicines.

Absolutely, they are. Many people that migrated from the public to the private system are having to pay out of pocket. Since public healthcare institutions have few medicines, people are being pushed to the private market. It is estimated that out of pocket expenditure has risen around 45 percent.

The inefficiencies in the public system do not seem sustainable.

No, they are not. And there are few indications of any solution in the foreseeable future. We are well into 2022 and still do not know exactly what the public system will buy, there is no consolidation of demand, nor appointment of any governmental agency to acquire the products – whether that is the IMSS, ISSSTE or INSABI. This is hindering the industry’s planning because they cannot close deals with the most important API providers.

Has this resulted in local manufacturers having to shut down?

Not at all. Companies that provided medicines to the public system are now selling to the federal institutions and at the same time to the states – in lower quantities but at higher prices since it is not possible to plan ahead for larger batches, simply because of economies of scale. Before the changes implemented by this government, we used to have public tenders that would last the entire year and the industry is now having to sign several smaller agreements.

What is your perspective on the reaction of Mexico to the COVID-19 pandemic?

It is hard to imagine a worse response to the pandemic than the one we experienced. Mexico’s healthcare professionals had the highest mortality rate in the world during the pandemic. Among the general population, the government’s official tally points to 350,000 deaths but if we look at figures of excess mortality, these are close to 700,000 deaths.

The pandemic was badly managed, in part, because it was heavily politicised. The response to the COVID-19 crisis was terrible. We must not look further than the delays in the acquisition of vaccines and their slow rollout in the whole country. It is estimated that only 60 percent of the population has been vaccinated.

Is the country’s economy suffering the consequences of this response to the pandemic?

It is not only the response to the pandemic. This government decided to focus on three landmark projects that, in my view, make little sense. The first was the halting of the construction of what was supposed to be Mexico City’s new airport, opting instead to build a less ambitious one in another location. The second is a train that will connect the southern part of the country but is threatening to destroy the jungle. The third is the construction of an oil refinery at a time when the world is moving away from fossil fuels. We see these as pharaonic projects that divert resources

away from more important areas such as health.

In 2018, the pharmaceutical industry was declared a strategic priority by the previous government. However, the current government is not focused on building internal capabilities for our industry.

What is the way out of this complicated situation for Mexico's pharma industry?

Despite the opening of new channels of communication with the government, I do not see them changing their mindset. The next two years – which will be the last two of President Andrés Manuel López Obrador's six-year term – will most likely continue to be marked by uncertainty. Hopefully, the 2024 election cycle will bring positive change for the country in general. This government has not tried to build bridges whatsoever with the private sector and the pharma industry was one of the first targets.

What message would you send to other industry executives in the continent and across the world about navigating the Mexican pharma landscape?

The Mexican pharma market remains very attractive, especially the private market. The country's geographical position is an advantage; we are working on a memorandum of understanding (MoU) with the United States to strengthen North America's supply chain and rely less on Asian imports. There is even discussion to bring API production to Mexico.

Yes, the Mexican industry is going through a period of uncertainty, but I believe we will be in a better position in three or four years. Companies are performing well despite the chaos. The industry continues to be strategic and a priority.

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