

# Interview with Rogelio Ambrosi, President, CANIFARMA

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There have been quite a few regulatory changes in the last few years such as the new drug registration process and the suppression of the local plant rule. COFEPRIS has also grown in power since it was started 10 years ago. What has struck you as the most impactful change over the last few years to the Mexican pharmaceutical industry?

There have been several changes in Mexico over the last few years, and most of them have had a large impact on the industry. One change that has dramatically affected the pharmaceutical environment has been the rise of generics: Mexico has always been in the generics's business, but in the last five years the Government has been encouraging the use of generics in the private market. We have even seen television advertisements about the change of prescriptions to generic medicines which are very much supported by the Government. The approval process for generics has been sped up in the last few years to reduce the time they take getting onto the market as alternatives for patients in the private sector. Generics have grown around 50% annually in the private market, while the overall market is growing at about 1-2%; they are the only source of growth at the moment while the market is stable.

The other significant change in the Mexican market has been regulation around Bio-Similars. Unfortunately a lot of them managed to get onto the market, and into Government tenders without strong regulation in place, but last year we were able to implement and enforce a law which has forced Bio-Similars through much stricter regulations and by May this year, any Bio-Similar produced or sold in Mexico will have been proven to be a high quality product. This will give companies certainty, and of course ensure the quality of future products.

With regards to the change in local plant requirements; everybody thought it would have a much bigger impact. However, we have seen some companies either closing their plants, or thinking of closing their plants, so now it is becoming relevant. To ensure that plants in Mexico stay in Mexico, we need to turn the country into more of a manufacturing hub to create a larger export market. In the long-term companies might close plants, and we know that some companies have been evaluating plant closures across the country.

The third significant change has been the COFEPRIS: it has now been recognised by President Felipe Calderon and the Minister of Health Salom3n Chertorivski as not only a quality controller, but a promoter of foreign investment in Mexico. The COFEPRIS can really be a growth driver in Mexico: Mikel Arriola has been given a lot of support and has done a great job in transforming the organization. The changes and processes put in place by the COFEPRIS will produce much better results for the industry- not only in the long-term but also in the immediate-term. Achieving recognition for new molecules and products in Mexico will be much quicker, and certification from the Pan American Health Organization is pending for April this year. They will also start the process of

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recognition from the World Health Organization before the elections in July, and in the long-term we need to have a mutual recognition with the United States and Canada.

Never before has CANIFARMA been so close with COFEPRIS. We have monthly team meetings to review each topic that we are working on together and further smaller meetings once or twice a month; it is key to work together like this.

What are the major priorities for CANIFARMA as an organization at the moment?

Since I started as President of CANIFARMA, the number one priority was to support COFEPRIS in doing a better job, and this is still the case. The second priority is to encourage the government to see the pharmaceutical industry based on the importance it represents in terms of numbers. We have had low profile exports for many years, and now we want the Government to help us to help grow the country. Another key priority is to harmonise the public health services across the different institutions. The treatment and medication you receive varies depending on the institution, so we as an industry are pushing for the same quality of healthcare across the board: for there to be just one Mexican healthcare institution.

We've seen a few Mexican companies go international over the last few years, such as Liomont and Sanfer, but not very many; especially considering the proximity with the United States. Why do you think things have happened so slowly?

In the past, the Mexican market was growing fast, prices were good and profits were high- there was not really a need to go into the United States because things were growing so well here. Mexican pharmaceutical companies have also focused on exports markets other than the United States; mainly Latin America. But it is clear that the landscape is changing- for example when we talk about the future, we talk about the North American market. If we provide just 5% of the generics that they sell in the United States, we would grow our business by 50% in Mexico! So there are a lot of people trying to do that now.

The full coverage of Seguro Popular is almost complete with 50 million Mexicans covered under a universal healthcare system: how do you think this has shaped, and will continue to shape the Mexican landscape?

The problem with Seguro Popular that we have as an industry is that we do not see sufficient volume, therefore we assume it could be 50 million people covered by the service, but there are not 50 million people receiving treatment and medication. Another point is that there is not systematic way for the Federal Government to measure how resources are spent in each state. So for us, it's very difficult as an industry to know how much medication Seguro Popular is buying, where they are buying from, or how they are distributing it; and if 50 million people are receiving treatment, the volumes should be higher.

Seguro Popular has been demanding very low prices in the industry. CANIFARMA is in absolute agreement with the Government to use generics, but perhaps we should find a different way of setting up prices. At the moment, we have tender business in IMSS or Seguro Popular, for example, and after those prices are set, they then apply to the rest of the market: this is not incentivizing the industry to participate. I think that it is a great idea, and it should be the future path of Mexican healthcare, but right now we need to make some changes to encourage the industry to participate. They can always import products, but at those prices it will be very difficult.

How do you think the perception of generics in Mexico has changed?

Since February 2010, all companies had to present their new dossiers to get drug approval, and I think since then the perception of generics has improved greatly. The new regulations were published and announced so many times by the former Minister of Health, so people started to

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understand the value of generics. Since then it has been changing: awareness is growing and it will continue to grow.

Do you see Mexico as following the trend that other emerging countries have shown, such as China, to be investing more in innovation and Research and Development?

I think that innovation will be the major market driver in Mexico. If we want to grow, it will not be through generics or through the Seguro Popular; it will be through innovation. We have strong patent and intellectual property law, and we also have NAFTA which is a valuable combination, but there is a way to improve and the industry is working on this. In the past, we were always expecting to receive innovation from outside the country, but now I know of many Mexican companies planning on providing their innovation from the inside, which could be new molecules, new combinations, or new uses of drugs. The quality of physicians and scientists here in Mexico is very high, and the cost of doing research is lower than in Europe or the United States, so there is a real effort to create a Research hub in Mexico. The opportunity is there, and we are moving towards it slowly. If you are able to innovate as a company, if you are able to differentiate your products, even with devices or services, then you will be able to succeed in this market. Competing solely on cost is starting to become less important.

What do you personally hope to achieve as President of CANIFARMA in the next 5 years?

I would like to make the pharmaceutical industry a priority for the Mexican government, and to be considered as a growth driver for the country. I also want to continue providing the hi-tech and high quality products that we have always provided to Mexican patients, and to be part of the COFEPRIS process to someday get mutual recognition and bring value to the country. This will help grow opportunities for CANIFARMA companies.

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