

Interview with Rafael Gual, Director General, CANIFARMA

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This is your third interview with Focus Reports. In 2004 and 2008 you were Director of AMIIF, before that you were Director of ANAFAM, and now we're delighted to be interviewing you as General Director of CANIFARMA with over 30 years of experience in the industry. There have been a lot of regulatory changes in the last few years, such as the purchasing regulations on previously OTC anti-biotics, the new registration process for drugs and the suppression of the local plant requirement for international companies. What do you see as the one most impactful change in regulation that the industry has seen in the last three years?

I think the main change has been the authorities' attitude towards promoting the pharmaceutical industry. The legal framework has not changed much, but the way government authorities have been communicating and working with the pharmaceutical industry has been tremendously supportive specially over the last year. They have really worked on improving processes and making them more efficient. From the 10,000 different regulatory processes that we had 9 months ago there now remain only 5,000.

COFEPRIS are starting to classify the processes by product quality, or by sanitary risk level. This is useful for companies because we have one administrative channel for low-impact processes and another channel for new molecules. Another challenge we face is the approval of COFEPRIS by the Pan American Health Organisation (PAHO) as a regulatory reference. That would allow companies to enter Latin American markets much faster; a win-win situation for industry and government.

The full coverage of Seguro Popular is almost complete, and with the Government pledging that generic medicines will form 80% of all state-purchased medicine, there has been a knock-on effect of both higher demand for generics and stronger price-negotiation in the public sector. How do you think this will change the way that both national and international pharmaceutical companies currently operate in Mexico?

As an industry, we don't really feel that Seguro Popular is working exactly as planned, or as we hoped. The prices they demand are very low and we don't feel that the purchasing budget assigned by the authorities for medicines has been necessarily applied in the right way. Another problem is the lack of accountability in terms of financial distribution.

In 2008, the Government abolished articles 168 and 170 of pharmaceutical legislation, no longer requiring companies to have a plant in Mexico in order to distribute their products. How have you seen this change in regulation affect national companies with more accessible entrance into the Mexican domestic market for international firms?

It didn't have a great impact. Only five international companies entered the Mexican market without registering manufacturing plants in Mexico, including Takeda, Genzyme and Amgen, and most of them are specialized in orphan drugs. The local plant regulation was only one of the requirements for companies to abide by, but we have a list of around 40 further requirements. European companies have been trying to penetrate the Mexican market, but the easiest way is to work with a local company, through mechanisms such as a joint venture, licensing agreements, or other kinds of partnership. The only difference now is that foreign companies can own their drug licenses, and in the past it was the local manufacturers that owned the licenses. They just had to sign a confidentiality agreement with the drug owners.

Some Indian companies came to Mexico, but penetrating the Mexican generics market is quite complex, especially the government market, because of a certain lack of infrastructure, and a lot of red tape. At the moment 5 or 6 Indian companies are present, but none with a significant market share.

What is your view on the prevalence of counterfeits on the Mexican drug market? What are the best strategies moving forward to reduce the problem?

It is very difficult to accurately evaluate the counterfeit market, but we estimate that approximately 10% of the local drug market is made up of counterfeit medicines which is in line with the World Health Organization's estimated country average. Although we are not above average, it's still a market worth US\$160 million, and companies are starting to try and combat it

by implementing security measures inside products including a bidimensional code, to track each individual product. I believe this could be the future for the industry in Mexico in this matter.

President Felipe Calderon has said that the Government is aiming to increase biopharmaceutical sector investment to 1% of the country GDP, it currently sits at 0.34%. What steps have you seen the Government take in order to fulfill this promise?

A few companies have received financial resources in order to support research and development activities in Mexico, and the main opportunities lie in Phase III and IV clinical trials. For these clinical trials, there is huge potential to be found in our Social Security system since it covers 50 million people, and every disease at every significant stage of its process can be found. The only issue I see is the approval procedure itself, which takes some time.

How would you explain the historically low levels of investment on R&D compared to countries such as Brazil?

It's a matter of priorities, and right now the Mexican and Brazilian governments have different priorities. In Mexico we are also focusing on education and very importantly on the fight against organized crime, which detracts resources from other areas, and Research and Development in the pharmaceutical and healthcare sector is no exception.

Recently we have seen some national companies growing internationally; such as Liomont, Silanes and Laboratorios Sanfer. Do you see this as a trend for companies in Mexico?

I think Mexican companies going international will be a trend if COFEPRIS achieves recognition from the Pan American Health Organization, the regulatory authority. Quality is always more important than price in the pharmaceutical industry. To give an example, if you have FDA approval on a drug, it opens the door for you to market it anywhere in the world. It is also one of our goals to turn Mexico into a pharmaceutical hub that produces directly for the U.S. market.

What are your recommendations for local companies aiming to go international in the short to medium term?

It's very important to achieve certification from the FDA, which demands an important effort in terms of work and time. I think requirements like Good Manufacturing Practices (GMP) are an excellent step towards fulfilling FDA requirements, because it's not a matter of quality for Mexican manufacturers, but a matter of time and expenditure in order to reach certification from FDA, and therefore penetrate the U.S. market.

What are your aspirations for CANIFARMA in the next 5 years, and which areas will you have a special focus on?

We are developing a plan for the pharmaceutical industry based on three major goals. The first is to achieve full recognition for our regulatory authority which will provide a strong opportunity for national companies to reach the Latin American market. The second goal is about innovation and research. We want to triple, or even quadruple investment in Mexican clinical research because we have so much potential to make it work with the Mexican Institutes of health, and Social Security. Our third goal is to make the Mexican pharmaceutical industry the biggest manufacturing sector in Mexico over the next 5 or 6 years. Currently pharmaceutical manufacturing represents 7% of manufacturing GDP in Mexico, and we want to push it into the first place. With the new administration, after elections in July, we hope we can put the procedures in place to reach these goals together.

If we come back in 5 years, what do you think will be the main changes for yourself and for the industry?

I must achieve the three objectives outlined above; it's also one of my personal goals. If we become the most important manufacturing sector in Mexico over the next few years, I will be absolutely thrilled! We also have to make the Mexican market the most important market in Latin America. Of course Brazil is a very strong competitor, but we need to consider that we have half their population. Of course it's not easy, but it's very important for us.

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