Interview with Mikel Arriola, Federal Commisioner, COFEPRIS

04.04.2012

Tags: COFEPRIS

It’s been one year since you were appointed as Federal Commissioner of COFEPRIS in March 2011. What have been the biggest challenges you’ve faced within this time?

The biggest challenge was to familiarize myself with the new agency, which has very wide powers as it regulates many industries. COFEPRIS regulates every sanitary risk relative to any industry so all in all, we regulate 10% of Mexican GDP, and 12% of Mexican international trade. The most important challenge I faced when entering COFEPRIS was the human challenge – and getting to know with whom I was dealing. There was a myth that this agency had to be administered by doctors or by people related to the medical or pharmaceutical business, and I came from the Ministry of Finance, so conceptually, that was the biggest challenge.

However, the first physical challenge was facing the huge backlog of sanitary registrations. We had a great legal reform in 2005 that mandated the renewal of every drug registration in the market to ensure that we had only 2 types of medicines: generics and innovative medicines. This reform was crucial, but also the main cause of the backlog as the government didn’t regulate this reform in administrative terms until 5 years later. Therefore in February 2010, when we had to face the deadline for renewals, we were not prepared. Under normal conditions, COFEPRIS receives 400 applications a month in terms of renewals and new registrations, and in February 2010, we received in a single month, more than 4000. This agency went into an administrative crisis, and an image crisis towards society and the industry. Therefore, I arrived from the Ministry of Finance and

had to deal immediately with the backlog. COFEPRIS issued 150 registrations in 2010. Between March 2011 and March 2012, we issued 9000 registrations, so I think we have met this challenge. We still have a lot to do but if you measure it in terms of value, those 9000 registrations represent 1200 million USD.

The other challenge was also to be very clear as to what we wanted in terms of pharmaceutical policy. Our pharmaceutical policy is to provide the patient – our main object of protection – with the best alternatives in the market. Therefore, we have to take out all the barriers to entry into the market to provide the best quality and the best prices. That's the goal of COFEPRIS and I think we are heading in the right direction.
Also, when I arrived in office there was also a huge myth about systematically challenging the opinion of the industry, seeing them as the bad guys and us as the good guys, but that didn't generate any positive effect to the consumer. The COFEPRIS universe was unreadable, lacking priorities, we needed to set them and to reset communication with the whole industry. We then also discovered other things affecting the market: one issue we had to tackle is the fact that companies needed a manufacturing plant to distribute their drugs in Mexico. Why would we assume that a company would invest in a manufacturing plant in Mexico to enter the Mexican market? We suppressed the manufacturing plant requirement, and in April 2011, we issued our first 5 registrations without this prerequisite.

Another strategy was to establish access to medicines for all Mexican families – so we started to issue sanitary registrations for generic drugs. Before that, we didn't have a strategy as a government regarding generics: we are the OECD country that spends the most on private health expenses, and the second worst in public spending. So since October, we have issued 109 generic registrations, covering almost 60% of the diseases related to mortality of Mexican population, and saving since October 2011 until March 2012 around 100 million USD. We are expecting savings of 1000 million USD in private and public money during the following 4 years.

What steps have you taken to actively change the reputation of COFEPRIS in the minds of the Mexican public, and in the pharmaceutical industry?

First we assumed that as a sanitary agency, we regulate several markets in order to protect the health of the population. In doing that, we are in the middle of several industrial and productive processes, so if we don't assume we also have the capacity to generate huge effects in the market, we are wrong. We have to generate predictability for the market, and send the right messages to our regulated industries, and by doing so, we are going to have a better set of alternatives for the consumer, hence protecting public health. We have to assume our position as a sanitary regulator,

but also as an economic regulator, and build strong relations with the sectors we manage. For example, we are now holding monthly meetings with CANIFARMA to discuss a growth agenda for the market which has generated a lot of solutions. I invest a lot of my time receiving companies of all sizes and, I guess, this is how the image of the institution has changed. We have been building a hyperactive agenda for the consumer; we need to be the best for the health of the consumer. The industry can't survive without a market, and we can't meet our objective to protect the consumer if we don't regulate firmly but with a commitment to both industry and consumers.

Indeed, we have heard many times that the Government should start to see COFEPRIS not just as a quality controller, but as a promoter for Mexican exports. How do you achieve this?

This year I have learnt that the Mexican pharmaceutical industry is an industry with great quality, and this is a huge asset for the Mexican economy. If we can work with the industry to expand their opportunities to invest internally and externally, we are making a change for our country. We have to be creative, and build the best profile for the Mexican industry to be able to attract more investment and provide better opportunities for the industry. We have to create a more flexible market and the best tool to create this is regulation and I want to be very aggressive in terms of gaining market share internationally. Mexico as a government has built the best economic situation in terms of macroeconomic policies and our economic structure holds better than other Latin American countries, including Brazil. We have the second best public deficit in the OECD region and Mexico is the third country in terms of inflation in Latin America; we have a balanced trade balance; a strong framework of free trade agreements; and we have been open since the 1980s to capital markets. If you translate this to the pharmaceutical market, it means we have lost our first place in terms of market size, but we want to win it again!

In its role as an economic promoter, COFEPRIS should gain recognition from the Pan American Health Organisation (PAHO) before the end of the year which will open up the door for Mexican exports to Latin America. Which steps has COFEPRIS had to go through and which steps remain to gain this recognition?

In 2005 Mexico launched a project with PAHO to harmonize regulators in Latin America, however, the first country to be recognized was Brazil, and then Colombia, then Cuba, and I don't know what happened to Mexico! Since June, we have started rebuilding our relationship with PAHO, and decided to initiate the process of recognition. The process is straight forward – it's an audit process. You have several indicators regarding authorization of vaccines and authorization of medicines, and Mexico was the first country to start the audit process in both sectors. We had the first informal audit in August, and the diagnosis was not good at all, which was probably the best

thing that could have happened to us because we started working much harder. The second informal audit in December was much better with an 8.4 out of 10 result. After reviewing the results of our third audit in March, we will decide on the date of our final exam – which will probably be in June or July. I'm pretty confident we will receive this authorization by this date, and if we obtain this recognition, we will have closed the circle in terms of modernization of the agency and implementing the best practices required by PAHO. As a direct effect of PAHO recognition, our documents are going to be recognized by Brazil, Colombia, and other Latin American countries which will greatly empower our exporters and take a lot of transaction costs out of their balance sheets. It's a very attainable goal. More importantly, COFEPRIS will be able to guarantee predictability, efficiency, safety and recognition by an external authority which is the fourth pillar in our work agenda. It will be an added value of President Calderon's presidency – to build a strong, comprehensive and recognized sanitary institution.

Realistically how far off do you see Mexico being from both achieving World Health Organization recognition and having mutual recognition from the Unites States and Canada? What are the major steps that both industry and the government will have to take together in order to reach that target faster?

PAHO is a branch of the WHO, and the process to gain WHO recognition will be very similar, so I believe that after gaining PAHO recognition, we will be very close to gaining WHO recognition. Therefore, PAHO recognition is the first step to send a very direct message to other regulatory agencies about Mexico. We have recognized several agencies for our internal processes – for example, we authorize products that have been recognized and authorized in other countries such as the US, Canada and Japan. If medical devices are FDA approved for example, we have a fast track system to authorize the product in 45 working days instead of going through a process of two years. However, that's only one half of what we want – the other half is recognition from these countries. But without PAHO recognition, thinking about international recognition for COFEPRIS is not possible.

As we have been discussing, the regulatory framework is a defining factor to assess the attractiveness of a market and boost the competitiveness of an industry. In this sense, how can COFEPRIS be a role model for other institutions in Latin America?

We clearly have to communicate the experience of COFEPRIS after we receive PAHO recognition and create a benchmark document. After meeting with a lot of counterparts in the world, the consensus within these agencies is that the authorization process is not, and should not, be related to productive processes, or the economy and the markets. The idea is that you can take whatever

time is needed to build comfort within the agencies, but nobody thinks about predictability or efficiency. However, you can have a safe authorization procedure with a very modern and transparent agency, dealing with the same incentives that the companies are facing. In that sense, we can be a model in terms of what we have achieved in our processes, and also in terms of economic mindset.

You are incredibly well-respected within the pharmaceutical industry – why do you think this is and what motivates you in this position?

The leadership within the pharmaceutical industry is one of the things that helped me the most to achieve what I wanted to achieve. I have found people with high moral standards, who are committed to the greatest value which is health, sharing the same objective as me: the well-being of Mexico and the Mexicans. I have had great experience with the leaders of this industry. I don’t think I am the important person here, I am thankful to them.

What is your final message?

We designed a very specific strategy when we first arrived in COFEPRIS, and I think we have been quite successful in complying and enforcing it. Firstly, we had to reduce the backlog, and we have since then issued 9000 registrations. Secondly, we had to improve our regulatory framework and eliminate barriers to entry into the market, which was done by issuing 109 generic registrations, suppressing the manufacturing plant requirement and building consensus around our regulations on biological products and bio-similars. Thirdly, we had to build international recognition, and we are in the process with the pending PAHO recognition. My conclusion is that we have a strategy to reinforce the Mexican market for the well-being of our patients and we are on the right path.

See more interviews