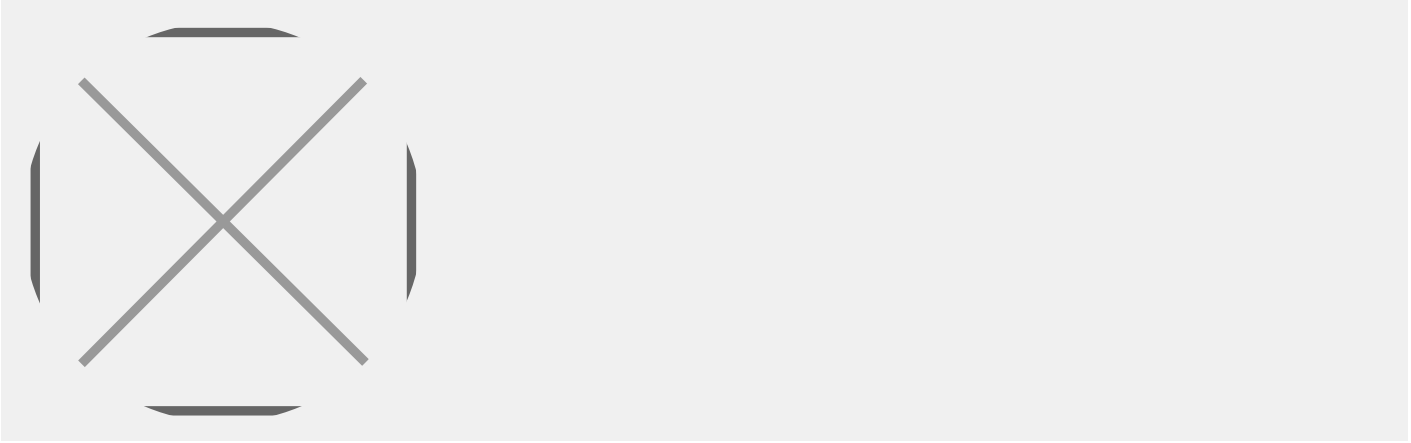
Interview with Ibarra Fernandez, Partner, Baker & Mckenzie Mexico



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The regulatory framework in Mexico is in constant change, and pharmaceutical com-panies are struggling to comply. What sort of challenges are companies facing when deal-ing with COFEPRIS and what must be achieved?

Permanent legal uncertainty and lack of transparency are the main challenges to re-solve. The first step would be to reduce the gap between Cofepris (The Federal Commis-sion for the Protection Against Sanitary Risk) legal provisions and day to day practice.

When filing a request with COFEPRIS, you are faced with two, often diverging, sources of information about the requirements that need to be fulfilled: internal procedures and COFEPRIS' website. Internal procedures are inconsistent in Mexico since they may change from one official to another. For instance, in the case of a transfer of a sanitary registration, the official may request additional administra-tive paperwork that was not specified in the applicable provisions or in the webpage. Since officials are not lawyers, they believe laws do not apply to them. Moreover, accord-ing to officials, the material published on Cofepris' website is legally binding, even though only provisions published in the Fed-eral Official Gazette should be binding to individuals and private entities.

One additional challenge is time responsive-ness from Cofepris. Once again, a gap exists between what is incorporated in the law and the actual timeframe. For pharmaceutical companies this is a real concern since no one in the industry knows how long a resolution will take. Before 2005, the sanitary registra-tions had no expiry date. In 2005 the govern-ment stated that all sanitary

registrations would have a validity of 5 years. Authoriza-tions granted as of 2005 and prior to that year had to be renewed in 2010. This measure caused panic, given the thousands of applica-tions they had to authorize at the same time and in the meantime the new applications could not process and created a very im-portant backlog.

The Fast Track health accord provides hope in facilitating the administrative process for companies who want to change the register for something minor – like modifying the name of their distributor or of their company.

Restructuring the whole system is complex, but Cofepris' commissioner is really contrib-uting to this change. Investors cannot invest in Mexico if they are not certain of registration times and requirements, so our legislation must evolve.

Could you develop on the strengths and specificities of the Fast Track Health Accord?

Between November 2010 and 2012, different health accords have been published in the Federal Official Gazette. The fast track health accord does not only reduce registration timeframes to achieve 30 days, but also rec-ognizes documents issued by Health Canada and FDA. On October 5th 2012, a new health accord was published regarding new regis-tered molecules produced in the US, Canada, Japan, Europe and Switzerland. The idea is that new molecules registered in those coun-tries, and new molecules produced in Mexico will benefit from the fast track system. Such conditions are necessary to promote investi-gation in Mexico.

The latest amendments contribute to reaching a mutual recognition between Mexico and other countries. This will facilitate filing documents, and allow faster processes.

Our northern partners have always been the first countries with which we have reached agreements given that a very large pro-portion of our trade is done with them. As Mexico entered NAFTA, it became more familiar with FDA requirements, language and documents. NAFTA enabled to create a similar mindset, made us familiar with their processes, and simply became our reference for trade. Mexico has a very comprehensive free trade agreement with Europe but the volume of trade is insignificant compared to the one with NAFTA.

Another measure taken by COFEPRIS to accelerate market access was the creation of Third authorized parties. What is your as-sessment on how impactful this has been?

Unfortunately we have not seen the impact of this measure yet, but I am convinced that soon the outcome will be extremely positive. The procedures will be facilitated and acceler-ated with the help of personal face to face meetings to resolve product queries and gen-eral doubts on the application review. Third authorized parties are extremely necessary since companies suffer from slow internal regulation processes, heavy competition, and tight schedules for product launch. But third parties must first earn trust from the compa-nies to potentially determine their future contributions.

Some of our interviewees raised the issue about how the national reserve in public tenders – which gives a 15% price benefit to products manufactured locally – is in contradiction with free trade agreements. From a legal standpoint are they correct?

It is important to separate the concepts of national reserve from the local manufacturing advantage of 15%.

On the one hand, countries may choose to have reserves in whatever they feel is appro-priate for their economy. For example, in terms of Free Trade Agreements, there are reservations set by each country in investment, services and government procurement. NAFTA had reserves in government procurement for the pharmaceutical sector and for certain goods which have been phased out. Any country is entitled to make this decision regarding its free trade agreements. If a country witnesses a sector where producers are more vulnerable, it may reserve this sector to insure its competitiveness.

Besides, there are provisions that are con-sistent with free trade agreements whereby it is possible to set the preference level to goods that are manufactured domestically. The United States has a Buy American act, where there are certain preferences in government procurement for goods produced in the country. Basically if you are a government the first place you want to buy from is where your local goods are produced. Of course, if no sourcing is available in the country, then free trade agreement countries represent the next logical step.

On the other hand, Mexico allowed Mexican suppliers to have a 15% preference in price above International bidders. The opportunity is that the Rules of origin which determine whether the product is Mexican do not re-quire 100% domestic manufacturing but only 50% (and a lower percentage in determined goods). This is a great opportunity since there are many different ways for companies to meet these requirements and achieve this 15% advantage. Nevertheless, importing products from abroad and assembling them in Mexico is not always enough to meet the 50% requirement.

Thanks to this, Mexico has a competitive posi-tion and wants to develop its investment opportunities with foreign investors. Inside Latin America, Mexico is much more transparent than many other countries, and its regulatory framework is improving rapidly.

What would be your recommendation to a foreign medium sized pharmaceutical com-pany penetrating the market?

There are many different challenges for for-eign companies entering the market. The first real challenge is to obtain a sanitary registry if the manufacturing plant is abroad. One option is to allow a third party distributor to first penetrate the market. However, it is common that when distributors are the title holders of the registry they do not want to transfer it. Since they already have the

contacts, and have solid relationships within the industry they want to hold on to the sanitary registry. Therefore, having a third party as the titleholder of the registry is risky, even with a contract. Another available solution is to do a joint venture to have participation in the company.

Another option is to acquire a Mexican com-pany that owns a manufacturing plant – even if the specific products you are going to sell are not produced in Mexico – and obtain the sanitary registry.

More options are available now, and recently the “soft landing” option has been a good opportunity. With a soft landing option, the third party acts as the titleholder and has an agreement with the foreign company. After a certain period of time, the third party will return both the registration and control back to the foreign company in exchange for a previously negotiated financial return.

Few companies in Mexico are willing to sell, because they know the value of their manu-facturing facility. Therefore, our advice would be to proceed with a combination of alterna-tives available, join forces with another com-pany, and most importantly solicit advising and consulting services from the right entities.

Mexico currently has a strong manufac-turing capacity, but various factors are threatening the country’s position as a manufacturing hub. Does Mexico still hold potential?

In Mexico, low labor costs, specialized work force, and fast learning candidates generate opportunities for the manufacturing sector. Maquiladoras have demonstrated business knowledge and efficiency in whichever tasks they initiate. Mexico’s economic stability and adherence to free trade agreements have encouraged investments in manufacturing facilities. Today, foreign companies are searching for safe investments and avoiding expropriation and closure risks, and Mexico is in very good stand. For instance, in terms of several Free Trade Agreements entered into by Mexico, in case of domestic measures that affect foreign investment, an international panel may review the case. Having legal cer-tainty on your investments carried out in Mexico is the most important competitive advantage of Mexico for foreign investors.

Many companies believe that Mexico compared to Puerto Rico and Costa Rica, is not competitive in terms of tax incentives when establishing a plant in the country.

In a small country like Costa Rica things can be moved at a federal level, whereas here we have both federal and local incentives. To invest in a country, companies need support, and ProMéxico (Mexican Federal Government agency responsible for strengthening the participation of Mexico in the international economy) is a very useful tool to bring them assistance. Nevertheless, it is true that Mexico does not offer many incentives on federal taxes, and certainly this may discourage foreign investment. The north of Mexico’s proximity to the US and the fact that we have Free Trade Agreements with most countries in America and Europe, can certainly balance tax incentives.

We were talking earlier about promoting research in Mexico. How can Mexico attract and conduct more clinical trials? Is the infra-structure the main bottleneck?

Recently, Mexico announced its ambition to be among the first countries to authorize product registration for new molecules – and has put all the regulatory incentives in place to become a clinical trial hub. In order to achieve this, infrastructure will need to be more developed to carry out more early stage clinical trials, as currently Mexico only carries out phases three and four.

The major issue is that companies carrying out clinical trials in the United States have been accustomed to processes and steps to follow and often have forgotten that Mexico has potential to offer. Mexican clinical trials done by public institutions would be much cheaper than in the United States, simply because of the high wages attributed to volunteers in the United States. In Mexico, a large part of the population would be willing to participate freely to the clinical trials as long as they were treated of their illnesses for free.

What would be your final set of recom-mendations to pharmaceutical companies about Mexico?

Our first recommendation would be to keep hold of their sanitary registrations, or have a very carefully crafted agreement when work-ing with a partner in the Mexican market. Then, if obtaining a registration is not the main issue in Mexico, meeting deadlines for these registrations certainly is. To smoothen the registration renewal process, it is neces-sary to improve general communication among the departments within the company, and it is critical for companies to assess when renewals are due. Finally, we would recom-mend investors to take a proactive approach to compliance, benchmark the competition and of course have the best advisors.

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