# Interview with Socorro España Lomeli, Executive Officer, ANAFAM

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This is your 3rd interview with Focus Reports. What would you say has been the biggest change that has shaped the pharmaceutical industry since we last interviewed you in 2008?

The main change in the last 4 years has been the close relationship that we've established with the authorities. Before developing this relationship we only communicated about problems that we needed to sort out, now it's a different story: they have completely opened up communications with the pharmaceutical industry, all the way up to Congress. This is an extremely positive change between the Government and the private sector: now we can be involved in the creation and implementation of pharmaceutical policies because the industry is listened to- we can voice our opinions and express our feelings.

There has also been a big step in communications between national and international pharmaceutical companies- they are now much closer than before. Agreements are made much faster than before, and while there are 2 or 3 topics on which they don't necessarily agree on, such as specific items on information protection and patenting, they agree on 95% of issues in the industry.

Do you think this is a result of more openness to generics or is it something to do with personal relations that you have for example with COFEPRIS?

Individuals in government, and especially COFEPRIS, have had a big impact. They have managed to overcome the traditional barrier between public and private sectors, and pushed communications forward. Secondly, I believe the improved reputation of the generics industry has helped to open up channels a lot, and now the industry as the whole is very open. The government listens to everyone- both national and international companies.

How have you seen ANAFAM as an organization adapt to changes over the years?

ANAFAM as an organization has adapted not only to technological changes themselves, but recent changes in the biotechnology sector and changes regarding new molecules. Quite simply, we have had to learn and adapt ourselves to run the industry race: biotechnology is the future and we are aligning ourselves to this pattern. Many of our companies see the future in biotechnology and are investing a lot of resources, both financial and human, in order to be at the forefront of everything that comes with it: technology, regulations, and good practices. We also have companies investing in generics and bio-generics.

In 2008, the Government abolished the legislation requiring companies to have a plant in Mexico in order to distribute their products. How have you seen this affect generic manufacturers now that entrance into the Mexican domestic market for international firms is more accessible?

We were worried that many foreign companies in Mexico that owned a local plant under government legislation would withdraw their infrastructure from Mexico after having that obligation taken away. We were worried that they would simply leave the country and find it easier to import, distribute and sell their finished products in Mexico, from abroad. Fortunately that didn’t happen. Actually in terms of investment in Mexico, nothing has really changed. The only thing that we have noticed has been a slight increase in products entering the market from abroad that our authorities don’t have the resources to regulate or monitor. The COFEPRIS had previously agreed that they would only allow entrance to medications where there is mutual recognition between the participating countries. They are working getting the Pan American Health Organization certification in order to equate themselves with authorities in other countries such as Colombia and Brazil. If they achieve recognition, it is more feasible for Mexican products to be accepted in other countries, encouraging mutual recognition.

In terms of manufacturing, how do you see Mexico competing on the same level as, for example. Brazil, currently the biggest player in the region? What is Mexico missing to get there?

Brazil has grown a lot and positioned itself as the 9th largest pharmaceutical industry in the world, unfortunately in the process, they outgrew Mexico. Brazil in this sense could be a good point of

reference for Mexico because their sanitary regulations are very rigid, and the quality of their registered drugs is very high: you can deduce from this that with more stringent regulations in place in Mexico, we can raise the bar and push up the quality of drugs being produced in, and entering, the country. If we had a stronger sanitary authority, the pharmaceutical industry could be much stronger, and with a weak COFEPRIS it is much harder. Other countries consider our regulations to be lax and that our products fail to meet the regulations that are in place elsewhere.

COFEPRIS is working closely with congress and the Ministry of Public Health to be recognized by the Pan American Health Organization and turn the Mexican pharmaceutical industry into a more competitive landscape, to move faster in the right direction, and to position ourselves at a global level like Brazil.

How are generics perceived in Mexico today? Is quality still an issue?

I truly believe that the old concept of ‘bad’ quality generics in Mexico was simply a case of rumour spreading because they thought innovative medicines were just better. It’s true that historically there was no regulation regarding bio-equivalence, and there was a lot of confusion between generics and similar, but since February 24th 2010 when they changed Article 376 of the Health Law, all medicines in the market or about to enter the market had to be checked, and those with below-standard, or no bio-equivalence, were removed. Since then the market is occupied by two categories: innovative medicines, and generics.

The perception of generics quality has changed substantially and we are also working in ANAFAM to position generics as high-quality medicines and with the companies that have invested in Mexico, we’ve supported them to help their medicines reach the required bio-equivalence levels. The authorities are also required to purchase generics for the state which has helped change the traditional reputation of generics.

Global companies that a few years ago were encouraging the development of new products are now the ones pushing for generics now. Between 2010 and 2012 many patents have expired and international laboratories have boosted their generics production- they are using their expertise originally intended for the development of new drugs. This means that no-one is trying to distort the image of generics anymore- they are all in the same market.

I think the last point I can make on the improved reputation of generics is that a change in legislation now requires doctors to write the name of the active principle on a medication prescription, and not just a brand name. This has helped the public to buy the generic product.

What do you think the next big changes will be in the generics market?

Already 65-66% of all medicines used in Mexico are generics, and furthermore many important patents are going to expire this year, such as Plavix, which will expire in July. Companies are anticipating the expiration dates so that they can develop and register the generic versions.

Since October 2011, the COFEPRIS has received and authorized 19 new generic drug registrations including drugs for cancer, cholesterol, and pulmonary emphysema. They have also received 44 registrations of 7 active substances, and they are liberating more registrations every month that will help the population with more accessible medicine.

In summary, the growth of the generics market will be very strong over the next two year because of all the patent expiries, and the COFEPRIS is supporting laboratories in terms of regulations, that want to make generics especially for diabetes, cancer, obesity, which are all increasing in Mexico.

Seguro Popular now covers 50 million Mexicans. Up until now what do you think could have been done better in terms of the relationship between the government and the pharmaceutical industry, on both sides? And what do you think has been done well?

I think Seguro Popular is a good scheme because it allows people with extremely low incomes that don’t have any kind of social security to pay for medical attention when they are ill. Seguro Popular has a wide-ranging catalogue of medicines and surgical interventions which are covered under Seguro Popular. However the system to apply those resources is de-centralized to each federal entity, and each one has their own local law, possibly inhibiting the resources to be distributed in the way that they were intended. Each governor can use the resources for what they decide, with no centralized control, reporting, or accountability for the destination of these resources.

Having said that, Seguro Popular is focused on purchasing generic medicines, and the relationship they have with the pharmaceutical industry is really excellent. I believe that in the last year it’s has allowed the industry to feel listened to, and to be a little bit more competitive.

Do you feel that COFEPRIS is achieving everything that it set out to do?

We do have a very good relationship with the Governmental authorities and we feel listened to, but perhaps we haven’t received the service that we should be getting from the COFEPRIS. We realize they are making a huge effort, because if they hadn’t, we wouldn’t have the appropriate processes and paperwork in place now, nor would we be receiving such good and timely responses from them, but they need to be stronger. They are responsible for the pharmaceutical industry, for alcohol, food, tobacco, and they just don’t have enough resources to maintain all of the areas, but

you have to recognize that they're making a big effort to go in the right direction, and that it's a very young organization having to deal with constantly increasing responsibilities. They are currently working on the integration of rules and regulations for biotechnology and new molecules, and today they published the updated laws on new molecules.

At the moment it's a difficult time because we are about to have the general elections in July, and while the COFEPRIS continues to work on overdrive, some individuals aren't taking many decisions at the moment because they are not sure if what they implement will be continued if government changes. It's a difficult time, but Mikel Arriola has promised to continue working and improving the situation up until the last minute.

The government has pledged to increase R&D investment in the biopharmaceutical sector up to 1% of GDP from where it currently sits at 0.34%. Have you seen this process start?

Unfortunately when the government announces their new yearly budgets, you start to realize from which areas they will cut funds: one of the areas cut the most was Research and Development. It's important that the Government increases Research and Development investment because it will help the industry to both advance, and to be more competitive as a country.

Aside from investment in Research and Development, I believe fiscal incentives are very important because they encourage industries to grow, and not just the pharmaceutical industry. As an incentive to export your product, the government could help you save money on paperwork processes or tax, so that you will be more competitive and grow more. I really hope the next government is able to play on the fact that while we have better research and education, the country will grow much faster.

What about Biotechnology companies in Mexico?

ProbioMed is a Mexican pioneer in biotechnology and has invested considerably in a biotechnology plant inaugurated around two years ago in Tenancingo. You could say that this is the launch point for biotechnological development here in Mexico. Other companies that are investing considerably to advance in biotechnology research are Psicofarma and Pisa.

Mexico is so close to the United States, why have we not seen more Mexican companies penetrating the American market, when you have Indian and Chinese companies from the other side of the world entering successfully?

When a company wants to export, they are often blocked by bureaucratic red tape and regulations which makes it impossible. It is mainly the administrative processes that pose a problem, not the

quality. Many years ago there was a program set up called “Administrative Simplification”, which caused a real tangle and made many regulations impossible to understand or adhere to. I believe there should be certain rules, but easy enough so that they incentivize companies wanting to export: they should not be regulations that I interpret one way, and you interpret another, they should be clear. This has been a big hurdle for Mexico in both entering the United States market, and some Latin American markets.

It’s important to note that there is corruption present in Mexico, which in many ways has stopped us from competing with, and being as successful as, other countries. Mexico is completely corrupted, but sometimes you just need one person, or one group of people that cause the problem. Regardless of this though, Mexico has continued growing, and we can say that Mexican products are good quality and are in line with standards set by other countries.

Where do you expect to find ANAFAM when we come back in 4 years?

I think you will find a very well positioned market, where generics play a major role. Unfortunately there are not many active principles any more, which is a shame for the whole world. We have discovered many but there are not many left, hence there will be many patents expiring over the next few years and generics will flourish. I also think our laboratories will be investing much more in biotechnology and research: Mexico will be a well-positioned biotechnology hub.

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