Interview with Dagoberto Cortés Cervantes , General Director, Hormona Laboratorios

22.05.2012

Tags: Hormona Laboratorios

Since we last spoke to you in 2008, Mexico has undergone a lot of regulatory changes, and we witnessed the rise of Seguro Popular, and the rise of COFEPRIS for example. What has been the biggest change in the market in the last 4 years, and how have these changes affected Hormona – either positively or negatively?

We could see a new pharmaceutical landscape shaping itself since 2005, which is when the law stating the obligation of all pharma companies to renew all dossiers and registers was passed. However, everyone thought that the February 2010 deadline was far away, and that 5 years was a lot of time to start the work. That’s the reason why a lot of companies faced problems, as they didn’t do their bioequivalence tests or made the necessary arrangements in the documents in time to be ready to submit their registers to the health authorities. This new measure came as a shock for most pharma companies because sanitary registers used to be valid for a lifetime. But this reform was an opportunity for Mexican pharmaceuticals – most countries already have adopted this 5 to 10 years renewal process. The population must be very confident that the quality of the medicine they take is the best available, and this new registration is a certification that all products available on the market have been manufactured under the same quality control. It was not easy to go through this change, but today in accordance with the figures presented by COFEPRIS, we have nearly achieved this goal.

Hormona’s revenues come 65% from licensed patented products and 35% from generics. How have you found the perception of generics evolving, and how did this affect the operations of Hormona?

10 years ago, the generics represented 3 to 5% of the market in terms of volume, but today they represent 58% and there are not many countries in Latin America with this important market share. Generics have been a very important government policy to address the economical challenges of the population. We have to remember that 10 years ago only 45% of the population had medical insurance, which means that more than half of the population had to pay out of pocket for medicines, doctors, hospitals, etc. Due to the rapid implementation of Seguro Popular, the situation is today very different. We have to take into account that 90% of medicines that Seguro Popular purchase is generics.

Hormona has been one of the most important providers of pharmaceutical products for the government sector over the last 25 years, so the evolution of the perception of generics has been very interesting for us to witness.

35% of our total revenues come from pure generics – or un-branded generics – and pure generics is a market niche that has been very interesting in the last 5 years. A lot of products, including blockbusters have lost their patent which represent an important opportunity for generic manufacturers. However in Mexico, a couple of years ago, the average time between patent loss and generic arrival on the market was 2 years. We believe that 2 years is too long, since in the US, the generic time to market is 24 or 48 hours. We had a lot of meetings with Mikel Arriola to raise awareness about this issue and today COFEPRIS is doing a great effort to reduce the time needed to issue a generic registration. In some cases, the time to market has been reduced to a couple of months before the generic registration is issued. This is very important for the authorities because it represents a lot of savings. COFEPRIS realized that their policies affected the economy of Mexican citizens and we celebrate this change of mindset.

Talking about COFEPRIS doing a lot of work behind the scene to promote generics, what are they doing to promote generics in terms of raising awareness among the population? For example, the US FDA distributes millions of leaflets every month. Have we seen this happening in Mexico?

We would have liked to do the same as the FDA, but this is not the case for Mexico. The generic companies tried to do just this in partnership with the health authorities, as taking this message to millions of inhabitants on your own is very expensive, but we never found an open door. Fortunately, due to the increase in market share of generics within the Mexican market – private

and government sectors- the health authorities together with the pharma companies have been very close in order to produce and create information to disclose this message to the population but we need to work harder to change perceptions. For example, people receiving generics from the government sector still believe that if they were given a choice they would go for the “better” product. But this is not true, as all pharma products today have proof of interchangeability, and have been manufactured under the same regulation. But people don’t know the quality control process has changed. Today, after the February 2010 new registration process, companies have reviewed their product portfolio and kept only their best medicine, so quality is not an issue anymore for Mexican generics.

When we had met you in 2008, you had just finished the construction of a new manufacturing plant, joining forces with Sanfer on this project, and you were telling us that the plant was built with a 25 years plan, and was only operating at 60% capacity to leave room for growth. How has your manufacturing strategy evolved over the last few years?

The government suppressed the manufacturing plant requirement in 2008. As a Mexican company, we of course decided to keep our manufacturing in Mexico but we knew we would be facing competition from foreign countries. Therefore, to remain competitive, we remodeled our plant and acquired more machinery in order to be more efficient. Efficiency is key. If you want to sell to the government which is very interesting in terms of volume but not in terms of value, you have to be efficient in your manufacturing. And this situation was a trigger for all Mexican companies to turn towards exports.

Exports are a good option for a country like Mexico because our manufacturing capabilities have increased. Companies which before the suppression of the manufacturing plant requirement would have never thought to export because they had enough business in the domestic market, are now seeing exports as the only option to survive. But if you want to export, you need to be ready to receive visits from foreign health authorities and comply with their regulation.

And this is when we faced another issue: how competitive is my dossier in markets like Brazil or Colombia ? Our surprise was to notice that no one recognized COFEPRIS as a health authority of high quality. And it was a shock to learn that Mexico was the country who initiated the PAHO recognition process but then we had let it go, while other countries like Argentina, Brazil, Colombia and even Cuba got recognition before us! When we realized this, we had a lot of meetings with COFEPRIS to discuss how important the recognition from other institutions was. Simply put, only once we get PAHO certification, can we be competitive in Latin America. We asked Mikel Arriola how the industry could support him to achieve this, and we established a work program in order to

reach this important goal. If all goes well, we should now be receiving this certification in August. This is a turning point for the Mexican industry. PAHO recognition has been the main priority of the Mexican pharmaceutical industry in the last years and will change dramatically the way we do business.

After COFEPRIS receives this certification, what would be Hormona’s first move in Latin America ?

Hormona already has subsidiaries in Colombia and Argentina, as these two countries are strategically important to enter other Latin American markets such as Brazil. Brazil today remains a big question mark for Homona, but is definitely in the cards for the future. Our Colombia subsidiary is well ranked, with total revenues of 28m USD yearly. They have their own manufacturing plant, which is not the case of Argentina, but we are on the way to get it. We can manufacture products in Colombia that we export to Mexico and vice versa. Before the PAHO certification, this situation has not been easy as COFEPRIS was not recognized by INVIMA and vice versa. To export products to Colombia, we needed to receive an audit from INVIMA, and we complied to all requirements regarding manufacturing standards, but when we presented our dossier t, we faced a lot of administrative hurdles – for example you need to show stability tests over 6 months instead of 3 months for a COFEPRIS dossier etc. Once Mexico gets a health authority recognized by PAHO all documents will be the same ones, and will follow the same rules, and that will allow more flexibility in our export business.

Talking about the other side of your business which licensing branded products, what would you say are Hormona’s main assets as a partner?

We talked about Hormona being a company with a top notch manufacturing plant, and we also have R&D activities which satisfies our local needs. For example, we are able to create new pharmaceutical forms, new dosages, new administration forms but we don’t have enough resources in order to develop or research a new product or a new API. Which is why, as several other Mexican companies, we look for licensing products. One of the main characteristics of Hormona is that in 2013 we will be a 80 years old company. This milestone means we have established a strong brand name and image with doctors, health institutions, authorities, etc. Everyone knows Hormona is a serious pharma company, compliant with regulation and we always make the best effort to produce best quality products. This means it’s easy for us to take a product and introduce it in the Mexican market. This is why we have received a lot of offers from MNCs to represent their products in the Mexican market. 65% of our total revenues come from licensing products. After 40 years of agreement, we have had the opportunity to buy some of the products over the years, so some of these prior licensed products are now part of our own portfolio.

Where do you see Hormona in 2016?

In terms of manufacturing, we are very eager to receive the PAHO certification as we foresee that there will be several new business opportunities to introduce our products in Latin America. We will use our manufacturing capabilities at full potential. Today, we produce pharmaceuticals, oncology products, antibiotics, syrups, pediatric formulations. But biotechnology is the near future of medicine in all countries and Mexico is the leader in terms of biotech regulation in Latin America and worldwide. Hormona is ready to be part of this market evolution. At the beginning, we'll be looking to license products from multinational companies. Then maybe, at a later stage, in order to be more cost competitive we could produce them in our manufacturing facility but for the moment, we are looking to license products from abroad.

See more interviews