Interview with Carlos EspÃndola-Scapetta, Senior Partner, EspÃndola International Consultants

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An expert in trade and regulatory issues relating to the pharmaceutical industry in Colombia, the senior partner of EspÃndola International Consultants offers his opinions on the steps taken by the Colombian authorities to improve quality and reduce corruption in the sector, as well as discussing the steps to maintain cost containment in a developing market, while still ensuring access to innovation.

From your expert perspective, can you give us a synopsis of the regulatory evolution in the Colombian pharmaceutical industry over the last few years?

Colombia has experienced a revolution regarding the pharmaceutical industry in that regulations were published in recent years to implement good manufacturing practices (GMP) for the manufacturing industry. This meant that the pharmaceutical industry in Colombia had to upgrade its plants and processes in order to reach international minimum standards for manufacturing, warehousing and distribution of pharmaceutical products here. Additionally, providers to the industry had to upgrade their quality standard to participate in the industry. EspÃndola had direct participation in the upgrading of at least four of the big pharmaceutical laboratories in Colombia. The firm actually launched the first international GMP practice for the pharmaceutical industry with the National Institute for Food and Drug Monitoring (INVIMA), in which more than 250 people from a number of countries came to Cali to participate and it was a tremendous success. This first GMP practice was one of the big launching strategies in order to align the Colombian industry to GMP in general.

Another issue is intellectual property (IP). Colombia has a number of regulatory issues. INVIMA has targets for the next few years with the industry, one of which involves managing sanitary risks. The other has to do with trust of the consumers in the management of that risk. Usually, the problem is specifically with generics. There is not so much trust by consumers with generic products for different reasons. In order to add value as a public entity, INVIMA has to develop trust in the consumer market of the industry. Furthermore, in order to participate more in international markets, the sanitary standards of Colombia must be raised.

INVIMA is the government agency that articulates the public, private and economic sector, therefore having a tremendous impact on the countryâ??s GDP. INVIMA is cleaning the pipeline of red tape, in order to simplify and avoid corruption. If the system continues to be complicated, the future will be costly and some laboratories might try to find a way out in order to comply with these regulations. They have advanced immensely and are much simpler to control. The most interesting thing about

INVIMA is, as a policy execution agency, they want to be facilitators of trade. The facilitation of trade is a demand-performance issue in emerging markets like Colombia. We have signed many commercial treaties and with the European Union treaty, there could be a tremendous opportunity for Colombia vis-Ã -vis European pharmaceutical companies. In order to lower the cost of production without losing quality, companies manufacture in Colombia using the benefit of these trade agreements. The most costly issue of any pharmaceutical product is research and development (R&D). Additionally, trade barriers are usually generated over prices and therefore medicines reach certain countries at very costly levels. As a policy execution agency, there is a big expectation as to what INVIMA can do as far as facilitating trade.

INVIMA already has tangible results due to this new policy formulation. That means that they have focused on offering a much better service to agents in the market. This means that risk management has been much more effective â?? less investment as far as management of risk, and the time of response in red tape processes in INVIMA has decreased which gives a better opportunity to the Colombian industry. While the system is fairly advanced, there is still much room for improvement, our investment in technological support for INVIMAâ??s laboratories and all the processes that they need to have in order to certify pharmaceutical products in Colombia. Sometimes the dossier for a product can be very difficult to certify because of the pedantry and lack of technology. Outside services are often used, which is not cost efficient. INVIMA has also developed a strategy through teams at logistics hubs to prevent the smuggling of pharmaceutical products. Additionally, INVIMA has invested in communications technology, which will change processes dramatically.

The Anti-Corruption Act of 2012 has been impacting compliance issues in the industry immensely, especially considering the fact that compliance is quickly becoming a key issue in Colombian business decision-making. Through the Anti-Corruption Act, I hope that the business and industry will change for the better. While the health industry in Colombia appears to be completely broke, the cost of licenses is vastly cheaper than other Latin American countries like Brazil or Argentina. You can see the difference in terms of what the cost is for having a new sanitary registry for a pharmaceutical product in Colombia. That does not mean that Colombia is more competitive; it means that it needs to develop better systems and INIVMA has to charge more than it does now.

From the legal perspective, what is your assessment of the impact of the health reforms by Minister Gaviria on the pharmaceutical industry?

One of the issues has to do with the purchase of medicines in high levels and volumes. The insurers (EPS) have unfortunately turned out to be financial companies instead of entities dedicated to promoting and sharing health services in a cost-effective way. The scapegoat in between, IPS, are the entities that execute all health programs â?? the hospitals, direct service providers, these are the people who have to negotiate with other providers, and they are paid by the EPS. While the structure that resulted from Law 100/93 is probably the best attempt I have seen to equally distribute health throughout the country, it is unfortunate that projects have been executed through EPS. It came to a point where employees in Colombia had to put their premiums into the system, which are obligatory and are discounted directly from the payroll every month. I am talking about billions of dollars that go into the pipeline of banks and financial institutions in Colombia, who do not give back benefits to the payers of the service. The government is now trying to save the system by making it publicly administered, as it was before Law 100. Given the amounts of money owed by the EPS to the IPS, and that the EPS and insurers claim that the government has not reimbursed them because of overpayments, there is no possibility to have this as a sustainable activity in Colombia.

In 1990, the constitutional reform meant that the Supreme Court lost the capacity to decide on issues that have to do with constitutional matters. The newly instated constitutional supreme court has within its structure the possibility of not only deciding if an issue is constitutional or not, but also

regulatory powers in order to extend or interpret what is the real application of a law. One of the most important constitutional rights that any citizen has is health. If my life is at stake because of health issues, the court will rule always in favor of me and will order the IPS to provide the service, which means that the financial structure initially designed for the execution of Law 100 has simply exploded. It is not only a problem of the EPSs and the way they manage the financial issues regarding health, but also what the constitutional court has done. We foresee a very complicated, long-term situation. There is a complete conflict of interest among all actors, including the pharmaceutical industry, which will still sell regardless of what happens. The business exists to be distributed amongst the players. In the next couple of years, we need pharmaceutical companies to drop prices in Colombia.

If they drop prices, what will this do for the country?

I am sure there needs to be an intervention in the prices. Multinationals make huge investments in order to develop new molecules that are eventually classified as medicines. We are talking about billions of dollars and, due to certification processes; you have a time scope of about four to five years maximum in order to make a return on such an investment. The more these multinationals produce, the more extensive the market is, the more volume you sell, the better return you have and then prices can start dropping. There is not much competition between certain molecules. Certain pharmaceutical companies are specialized in areas of health, which produce developments that penetrate the market. The financial situation of these companies is sound, because of the levels of investment in new products. In contrast, it is the cost-management of the productâ??s price in terms of raw fiscal materials that is the most expensive aspect and the biggest issue.

Multinational companies do need to drop prices in spite of the fact that they invest greatly. But local companies have not made those investments at all, and they do not only produce generics â?? they have products that have developments from a second level patent that they have produced with commercial names in Colombia and they are tremendously expensive. An active principle can be bought as a generic anywhere in the world and prices are flexible because the market offers everything. Importing an active molecule into Colombia and then use additional local packing and blistering technologies result in a pill that costs COP 800-1000. However, multinationals can make billions with generics with a commercial name (in which case they are no longer generics).

The end consumer has to pay whatever any local or international company decides to charge, and thus does not have a choice. There are about four companies in Colombia that are reliable for generics; the others simply do not have the volumes of generic products that other players have. Given the vast difference in price, generics are fundamental here. For example, all of Sanofiâ??s takeovers have been to go to top-quality generics.

Could you highlight a couple of the main cases that you have dealt with that you think showcase what is going on in the industry right now?

EspÃndolaâ??s participation as a law and consulting firm has been focused more than in cases of court, resolving situations. The firm has been involved with trade and regulatory issues dealing with imports and exports. One of my most interesting cases involved Sanofi restructuring all its logistics regarding distribution and manufacturing of products in Latin America. The company decided to set up in Cali and, in terms of capacities, focus on exporting from Colombia to Brazil, which is usually the other way around. This illustrates that there are different ways to structure business to be competitive. Free trade zones (FTZâ??s) in Colombia have very good incentives regarding taxes and the payment of duties. According to foreign trade laws and pharmaceutical industry regulations, there are certain strategies that can be built in order to complement the benefits that you can get from FTZâ??s and simultaneously use the installed capacity you have out of FTZâ??s. Ideally,

someone would build a facility within a FTZ, but that is not the case in Colombia, and the reason for why most production has left Colombia. Upgrading 50-year-old plants would be too expensive and cannot be simply moved to a FTZ. Up until five years ago, all the profits made on shipments from FTZâ??s to third-party countries did not pay taxes in Colombia. Now they pay 15 percent. There will be a change vis-Ã -vis 32 percent that you have to pay if you are out of the FTZ. Now, FTZ facilities could be used for logistic issues. Active principles could be brought into the FTZ. According to law, you can bring products into FTZâ??s up to a maximum of six months into Colombia, process them partially in a local facility, ship them back to the FTZ, finish the product and ship it out. EspÃndola has been a business-structuring law firm in developing different types of tools for IP issues, logistics and trade that can be used within the industry.

What is the one main challenge for your customers in terms of helping them navigate the Colombian pharmaceutical landscape?

You have to be very conservative with regulatory issues. If you want to last in the business, you have to invest in regulatory matters. You also need to focus on new opportunities that trade agreements are opening for different options. The industry is a little laid back regarding starting opportunities that can be found with European Union commercial treaties. If Colombia upgrades its regulatory framework, the country can compete with Europe. Active principles comes from the EU, US or Japan; using trade agreements, the heaviest cost would be the import into Colombia, where the ingredient is transformed into medicine, and then shipped back to its origin from Colombia with no customs duties at all. Colombia has lower labor and land costs, which is where the country can start competing. Colombia has been a very steady market for the industry. Having worked for 42 years, I have never seen a pharmaceutical company go bankrupt. There is definitely a market share and profit here. If Colombia is very aggressive with proposals, the countryâ??s future will be with importers and commercialization of the pharmaceutical industries, in spite of the countryâ??s history as having a solid manufacturing industry.

If we were to return to Colombia in the next three to four years, are there any goals that you would personally like to have achieved?

Colombia needs a government that has the guts to make certain decisions using the Anti Corruption Act to really cut off corruption, which is probably the worst situation the industry has. I also hope that that INVIMA focuses on implementing compliance issues, which are lagging. Companies that focus on compliance first might lose market share at the beginning, but will have tremendous opportunities in the mid-term. If this is not done locally, foreign companies will take over. There are very few local players left and the smaller ones risk being bought by multinationals. Essentially, I would love to see compliance and anti-corruption measures taken effectively.

What attracts you to the pharmaceutical industry?

EspÃndola has a very strong presence in international trade. Within that, we have specialized in certain strategic sectors that need to be developed and help within the Latin American countries. The pharmaceutical industry came to my attention 25 years ago, when I learned how fascinating the research processes and structures to improve human life quality were. I also had the opportunity to visit the most cutting-edge development laboratories of certain pharmaceutical companies abroad. If you want to benchmark quality, you have to look at the pharmaceutical industry. Nothing is more demanding than producing vaccines or antibiotics. I also had positive experiences on the commercial side, helping companies to structure strategies to approach the market in the most effective way possible.

While there is room for improvement, the Colombian regulatory authorities are doing a fantastic job. Human resources in Colombia can be competitive anywhere in the world. Colombia needs to determine how to develop manufacturing sites within the country and exploit all the opportunities that foreign investors have here due to the stable political situation. Free enterprise is well-respected. The legal and tax framework has improved significantly in recent years. Colombia also has two coasts, and thus the opportunity to market itself to many different parts of the world. Colombia also produces for regional markets, which are sound. I would invite people to look at Colombia as an interesting opportunity to engage in pharmaceutical and health businesses, either to manufacture or distribute.

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