Interview with Alberto Bravo, President, AsociaciÃ³n de Industrias FarmacÃ©uticas Colombianas (ASINFAR)

22.03.2013

In 2010, you told Focus Reports how the price of generics in Colombia is the lowest in the Latin American region because of competition from pharmaceutical labs. Could you tell our readers what have been the principal accomplishments from the pharmaceutical industry in Colombia in the past three years?

ASINFAR represents the Latin American and Colombian pharmaceutical industry. I refer to the Latin American industry because there are several foreign companies who have acquired local businesses but have maintained their original production within the country. This means that there has been no loss of employment and the pharmaceutical industry has been able to remain and grow within Colombia. Like every other major industry, pharmaceuticals suffered through a recession last year, but the demand for such products continues to be very strong because of quality and affordability for Colombians. 70 percent of demand for products in both the retail and institutional markets is for national brands and generics.

However, Colombia still suffers from monumental disproportions. Multinational companies, especially those with major biotechnology products, have seriously affected the finances of the healthcare system. A small number of units are monopolies, either because they are protected by patent or data protection laws, or because they have no competitors on the market because of INVIMA, who have closed the door for biosimilar products in the country. The health budget has now been structured to fulfill whatever is required by law, or whatever the scientific medical committees determine is required in order to take care of certain pathologies, especially those of medium and high cost. This means that billions of pesos are being channeled into a small segment of the population. I am not saying that we should exclude certain diseases from having proper medical attention, since a diseaseâ??s treatability is irrelevant; I am saying that the pharmaceutical monopolies are breaking the healthcare system. This issue is not specific to Colombia; rather, it is a global problem.

Despite all of these issues the national pharmaceutical industry has been able to grow, but its growth has been stunted because it has not been able to compete with the latest and most innovative products, like those in the biotechnology field and biological vaccines.

The Ministry of Health recently published the third draft for biotech regulations. What is your perception of this third draft and how do you think it will influence the industry?

First of all, the third draft is much worse than the second one, which logically means that the second one was way worse than the first.

Due to the pressure exerted by multinational firms, the government has not ratified any law that would benefit all the actors within the pharmaceutical industry. Instead, it is caving in to the pressure

these multinational firms are exerting. Sometimes this pressure is also exerted by their respective country governments and ambassadors. Even though this last draft aims to clarify that there are three ways to acquire a license for a biosimilar, in most cases these products are simply recycled and there is no major technological advancement made with them. This is very concerning, considering the government has paid hundreds of thousands of millions of pesos in extra costs because of these monopolies.

If you could suggest to the government three key elements they should consider when drafting biotech laws, what would they be? Are there other models in other countries that Colombia should look at?

Colombia wants to use its own model. Our model combines elements of the Food and Drug Administration (FDA) and the World Health Organization (WHO). The Colombian government has brought in an Argentine consultant named Mauricio Seigelchifer. He has been called upon to become one of the permanent advisors for the WHO. This scientist and other experts are promoting a balanced and strict law for the concession of records for biosimilars, especially the most complicated ones. However, this allows for a healthier market by preventing commercial barriers to develop. Biosimilar companies have demonstrated that they are better innovators, which has forced them to review their norms which were very anticompetitive and led to the creation of monopolies.

Minister Gaviria has stated that there will be very strict reforms to the healthcare system based on Law 100/93, and the changes to the powers of the EPS which introduced the differential pricing. How do you think these reforms affect the industry, and will generics and innovators be able to coexist?

ASINFAR supports these efforts. This organization is clear when it supports or criticizes an issue. ASINFAR has been honest and supportive because the association wants to find a solution to all the problems the system is experiencing.

The first step is to support all of the initiatives. But what has happened is that the Health Ministry has changed its position somewhat in the last few months. At first the Ministry wanted to create a statutory law, but then decided to reform Law 100. This law has two major reforms which are Laws 1122 and 1438. Today, the Minister wants more of a structural reform. This has been postponed (though not entirely abandoned) due to scheduling issues. The legislature will theoretically be picked up again once congress resumes its activities on March 16th.

ASINFAR also supports the notion that insurance companies should be thoroughly analyzed if they are to coexist as an important component of the system. This association would not be either in favor or against them, but I do think it is necessary to run a proper analysis to determine their contributions to the industry versus costs. These are resources that should be employed by the Ministry of Health, which cannot wait any longer and it wants to impose a new reform.

The state of ASINFARâ??s relationship with the multinational industry is worse than ever. This became evident during the Free Trade Agreement discussions with the United States. The multinational industry in Colombia, like the rest of the world, wants to eliminate its competition. Even though we can all coexist, local businesses cannot coexist with the strong international industries. Colombia is the only country in Latin America with well over 70% of the market per units. We have discrepancies regarding intellectual property rights, as well as with control over pricing. In this sense, the emphasis is given to the pharmaceutical industry, which seems to try to discredit generics as part of their work.

National pharmaceutical laboratories produce 75% of the drugs required for internal consumption, while also generating 95% of national drug production. Do you think that

manufacturing firms in the pharmaceutical industry receive the support they need from the government? What are the main challenges that these laboratories are currently facing?

Aside from a few exceptions, national pharmaceutical laboratories do not receive the necessary support, whether it is economic or via incentives. Every day, the Administrative Department of Science, Technology and Innovation (Colciencias) keeps reducing the budget that should be employed on joint projects in which the private sector is willing to make contributions to put several projects in motion that the government should be implementing. There are a few pharmaceutical research centers that have had their budgets slashed every day. Furthermore, the previous director for Colciencias comes from academia and is also a member of a pharmaceutical research center which was funded by ASINFAR. He was the chancellor of the University of Antioquia, and back then he was a politician.

At one point, ASINFAR had to reconvert and adapt all of the plants in order to meet all of the government standards. This is a daily job, since government inspection officials from INVIMA always apply the strictest and most current norms. Thus, ASINFAR always has to be on top of these changes, which means that, in practice, we have some of the highest standards out there.

Aside from the fact that they do not cooperate with us, they are also very generous with the perks they grant, like with what the Superintendence for Industry and Commerce does when violating Andean laws by pushing the limits of intellectual property rights. Last year, a patent manual was issued and now some patents are being called â??Express.â?• This means that the necessary studies for patents are not being done here, completely violating the Andean Law. In Colombia, as in Ecuador and Peru, supranational law supersedes all of the individual protection laws. We also find that there is little to no concern regarding the regulations that are approved, especially those by the Superintendence for Industry and Commerce and the Ministry of Commerce, which is just a paper entity. Our only redeeming option in which ASINFAR is heard is the Ministry of Health. But we need more actions and not just a listener for our concerns, since this association does not receive any benefits.

What are the principal challenges for the laboratories at this moment?

The threat from the actions that the Superintendence for Industry and Commerce has taken are so illegal that our pursuit for legality means to nullify the new patent manual which would allow for extending the range or amount of products that are protected by law. This would mean that an innovator with patents rejected due to insufficiency or an applicable utility for the industry will now be granted these patents by the Superintendence. Instead of using our resources to strengthen human resource talent, or our cooperation with multilateral organizations in order to develop new products, we are now forced to employ these resources to hire lawyers to fight this.

Instead, the companies that have acquired resources and funding have done so through international financing institutions and credit organizations. Recently, a local company has been working with the Bank of Colombia in order to acquire credit, and to allow the bank to become a decision-making partner. They are doing this instead of applying for a loan they will later have to pay. Here every industry has to move with its own resources.

What have been some of the efforts the industry has taken in creating a positive impact with the environment during the past few years?

This is a topic that is managed by the National Business Association of Colombia (ANDI), but we form part of a comprehensive committee. Due to logistical and operational reasons, we have ceded control to ANDI, since there are many requests that come from the Ministry of Environment regarding containers, package recollection, waste disposal, etc. ASINFAR is also working on a

campaign that aims to educate citizens regarding the proper way and locations to dispose of medical waste. Improper disposal sometimes leads to serious pollution problems.

What is your vision for the future of the pharmaceutical industry in Colombia? What are the key elements and priorities in Colombiaâ??s agenda for the next three years?

We want to strengthen our R&D. We want to maximize our natural resources in the field. For example, the existing biotechnology regulations allow the industry to grow. My main goal for the next two to three years is to push to eliminate all obstacles for commerce; to convince the government and INVIMA that the pharmaceutical industry is a key industry in civilized countries. We have requested to be considered a key industry because we have a deep impact on the GDP. Additionally, ASINFAR grants the country the power to be able to treat the most pressing illnesses that can afflict any citizen and resident.

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