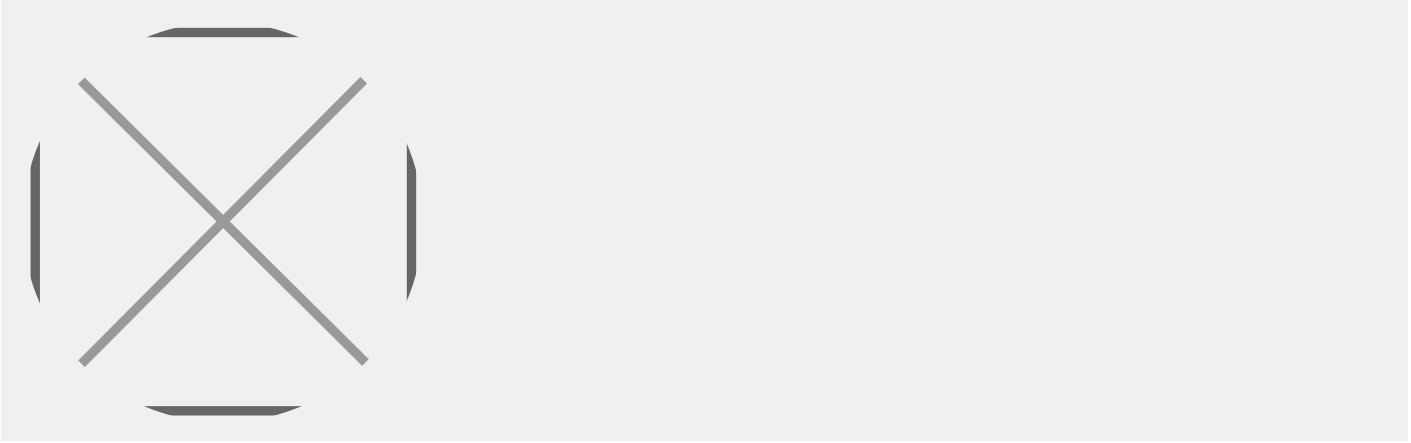
Interview with Francisco Paula de Gomez, Executive President, AFIDRO



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When we interviewed you in 2010, you mentioned that “while Colombia has had a solid transformation of the health system in a short time, being a model of success for Latin America, with 93% coverage of the population, it is time for the pharmaceutical industry to become a true player. In order to strengthen their position international labs have to review their portfolio, their price strategy and business strategy.” As a way of introduction for our readers, could you describe the main achievements and developments in the pharmaceutical industry in Colombia over the last three years?

The current scenario of the Colombian healthcare system is one of perpetual evolution. At the moment, the entire health system is under review, and the next few months will prove to be critical to the future of the system and the industry in the country. This is actually the first time in which the government has indicated that such a drastic change needs to take place in Colombia. Among several issues, perhaps the most important aspect for the industry is the reference pricing system for medicines.

That being said, there are some doubts about the future of health in Colombia, whereby the Government must make an extra effort to demonstrate we are on the right path to ensuring that the healthcare system here is one of the best in Latin America. Many people in Colombia are looking positively towards the Health Ministry as leading the way to this goal, and 2013 will indeed prove to be a critical year in achieving the tasks set before the Ministry. Colombia has quickly

become a country for endless opportunities in most economic sectors but in this regard I think that the health sector is lacking and it is yet to reach the same standard.

In September we saw the appointment of Minister Gaviria for Health and Social Protection. In your opinion how would you rate the government's current commitment to create a business environment that is attractive for business and for health innovation?

Minister Gaviria is a recognized economist in Colombia, and he is well-qualified to take on the demands of his position. Business is of course very important for this sector, and I hope that he, President Santos, and everyone else involved will be careful in developing and enforcing policies that encourage more active investment in the healthcare and pharmaceutical segments. In terms of innovation there definitely needs to be more communication between the private and public sectors. That being said, Colombia must maintain a healthy, attractive and open environment for such investments. In particular, it is necessary to reach equilibrium between the necessities of the Health System and the market.

Colombia in general is very important for the region. The country is strategically located in a gateway position between South and Central America. Its professionals are generally well-educated. Compared to many other countries, particularly those in Europe, Colombia has survived the economic crisis quite well, and the economy here has grown in the past few years due to carefully laid-out measures taken by the government.

The top priority on Minister Gaviria's agenda is the strong reform for the health system, from changes in the Law 100/93 to the characteristics of the EPS up to the introduction of the reference price system. How will these reforms impact the industry in your opinion, and how do you think that these reforms will help the coexistence between generic and innovative producers?

Colombia presents a tremendous opportunity because in that last year the government equalized both regimes, Contributive and Subsidized. This has helped to grow the market. As in most countries, innovative medicines are very important to the Colombian pharmaceutical industry because many of these drugs cannot be found in the generic market. Many innovative companies have announced that they are integrating high quality generics and biosimilars into the Colombian market. Generic drugs still control a significant market share in Colombia, and it seems that this portion of the market will grow as well.

The Ministry of Health has published a third draft of the proposed regulation for biotech drugs. In 2010 you told us that there was no formal regulation at the time and development was marginal while a stronger regulation was needed to develop the sector. What is the position of AFIDRO with respect to the latest developments of the regulation of biotech drugs and how do you think this will impact the industry and your members?

Unfortunately there are still no biotech regulations that have been concretely implemented in Colombia. The current administration has proposed that Colombia needs regulation to stimulate competence. In my opinion we are talking about a sanitary regulation and the minimum set of regulations must be according to the prerequisites of the World Health Organization (WHO). The Colombian government has published its final draft and some articles do not reach the minimum WHO requirements, unfortunately. There is high concern for AFIDRO on this topic. The association recognizes that Colombia needs a formal decree on biotech.

Furthermore, I believe that in order to promulgate growth in this area, there needs to be a greater number of companies and medicines in the market, particularly innovative biotherapeutic medicines and high quality biosimilars, and not just some questionable medicines whose origins are in some process of biotechnology. Additionally, it is crucial that Colombia ensures a correct regulation for biotherapeutics
In terms of medicines produced from chemicals, you need assurance on bio-equivalents. But when you are talking on biosimilar therapeutics, you need to demonstrate through clinical trials that your medicine is similar to the leading brand.

If you were to suggest a model to the government in terms of what is needed to be done in order to portray Colombia as a biotech player, where should Colombia look?

It is important for the Colombian pharmaceutical industry to decide on which innovative medicines to produce, import and export. That being said, Colombia does not have the big markets that Brazil or India have, and it is very difficult for the Colombian market to be competitive with those of much larger countries. As I mentioned, innovation will play a key part of the pharmaceutical industry here. It truly is the perfect sector for the country. While generics will continue to play a key role in the market, simultaneously you can develop innovative technologies that make drugs more competitive.

One of the main objectives of AFIDRO is to work closely with the government, to consolidate the already great innovation context, to strengthen the social responsibility of the industry and to attract more international labs to Colombia. In trying to be an effective association and positively influence the environment for its members, what have been the main achievements in the last three years for you?

The government certainly experienced many difficulties a few years ago, leading to the declaration in 2010 of a health emergency. Many believe that this was done out of desperation. The constitutional courts declared that this emergency was unconstitutional. AFIDRO had spoken with the government numerous times for clarification on a number of issues; for example, does the government believe that the reason behind the crisis is the price of medicines? Realistically though, medicines in the health sector only comprise 14-15 percent of the market. For AFIDRO it was very important to clarify that to the government, particularly in regard to the different healthcare stakeholders. Eventually, Colombia's political leaders realized that problems in the pharmaceutical sector affect the healthcare sector, and this is not even the main reason for the crisis. For politicians to understand this basic principle was an achievement!

At the moment the Colombian Health System is in a critical point because the government is in the middle of either changing the system or maintaining the model with some new changes. Generally speaking however, I think that the Colombian health sector has been successful because while the country has a low to medium income, the 95-96 percent health coverage of the total population is very unique for Latin America.
It is important to collaborate with the government and with other actors or agents in the economy and in the system in order to clarify the best possible policies for Colombian healthcare. The healthcare industry generates work opportunities, education, and knowledge, and it is important to continue this generation. This can be achieved through cross-functional collaboration. For instance, we would like to continue our partnership in the Organization for Economic Cooperation and Development (OECD) to maintain treaties of trade.

You mentioned that AFIDRO and the industry should collaborate with the government and all the actors in improving the industry and the state of healthcare. What are the main priorities on your agenda for AFIDRO today?

The most essential priority is that the health system in Colombia maintains equilibrium and then offers access to the patients. This is fundamental for the country to continue successfully. If you do

not have a consolidated health system, this will present a whole host of problems for pharmaceutical businesses. In terms of prices, the government plans to have a new regulation for reference pricing on May. This will be very important for Colombia as we have a free market here, and only create regulations that are strictly necessary. Essentially, the next two or three months will be extremely important for AFIDRO, particularly in regard to the level of biotech regulation that will be issued. Pharmaceutical policy was drafted last year, which has lead AFIDRO and other actors in the value chain to a window of opportunity. Innovation has become easier to create here, and investors are increasingly attracted to the country.

What is your vision for the next five years, and where do you want to take AFIDRO in that time?

It is my hope that Colombia will make the right decisions in health, the pharmaceutical sector and in economics in general. The entire country is gradually growing and this is set to continue in the next few years. The primary goal for the time being is to provide universal health coverage to all of Colombia's citizens, which the system is very close to completing. On a secondary level, the quality of healthcare services in Colombia needs to be consolidated. In order to do this, the country needs more qualified treatments, medicines, and technologies. This will take place over the next five years. At the moment, the government knows that regulations on quality, security and efficacy need to be improved, and politicians and industry leaders will be working hard to attain this. Better medicines and technologies will lead to the creation of more projects and thus require more capabilities. Colombia will continue to import medicines, but will also produce more medicines, both innovative and generic.

AFIDRO will be leading a new opinion on the health system in the next three to five years. Unfortunately in Colombia, there are stark contrasts in opinions over exactly how to progress in this sector. AFIDRO wants to collaborate with the whole country, and provide explanations or proposals about new developments in health in general. The innovative industry is aware of this, and AFIDRO is committed to assisting everyone in Colombia with health issues. New ideas are needed here, and despite differing opinions, it is my hope that everyone will find some common ground.

When you find darkness, someone is needed to start a little light. I will try to collaborate with the finding of that light.

You have been in the health sector for more than fifteen years, with a wide array of positions from university, to hospital, to government to multilateral organizations. You

are still here since the last time we saw you – great consistency. What is it that is your main motivation with AFIDRO and what do you think is your personal mission for the association?

The association is not necessarily to make big business. I believe that I will help my country in creating new and consistent ideas. Colombia is only waking up after many years, and thus many more people are needed to instill growth in the health industry. I am only one person, and we need many people to produce ideas and discussions in a civilized way. My experience is in surgery, public health and economics. When you have these kinds of opportunities to make change based on your personal knowledge and experience, you have a real responsibility.

What would be your final message for our international readers about Colombia for Pharmaceutical Executive?

Look to Colombia.

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