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Besides protecting the health of Mexicans, COFEPRIS today offers an important value-added to the investment community: predictability. The organization's commissioner shares the astonishing results of his last three years of tenure, undertaken with the priority of improving access of the population to a well-supplied drug market and making the Mexican pharmaceutical industry a much more attractive investment destination.

When we interviewed the most important industry players back in 2012 everyone was worried about you leaving at the end of the past administration, so we are very happy to see you still in charge. What has been your number one priority since then?

Since I was appointed as commissioner back in April 2011 I have always been firmly convinced that having an efficient and transparent authority could only generate growth in the industry you regulate – whatever this may be. First of all, the authority must protect the Mexican consumer by ensuring the safety, quality and efficacy of all products it regulates via science-based evidence. Besides this, one of our main goals is to create the conditions to drive growth in the pharmaceutical industry – and access and efficiency are crucial to ensure this. In several countries we see regulatory agencies, which are neither efficient nor transparent, sometimes even as a strategy to protect the local market – this is not the case of Mexico anymore.

Back in 2011 the main problem was the backlog COFEPRIS was facing, as a legal reform in 2005 mandated the executive branch to renew around 25,000 drug registrations and the authority was not complying with the task. By 2011 they had only renewed 153 registrations, which presented a difficult situation upon my arrival. As of today one of our achievements has been catching up on the backlog by renewing these 25,000 registrations in less than three years. Today COFEPRIS' priorities are aligned with the health policy established by the Federal Government, whose main objective is to improve access of the population to a well-supplied drug market that offers innovative and generic medicines at the most affordable prices.

How is COFEPRIS improving access to treatment and how do you make sure to keep the balance between generics and innovative drugs?

After the renewal of the registrations, we decided to implement a two-tier strategy to improve access to both categories of drugs. From October 2011 to 2014 COFEPRIS released a total of 31 active substances, which correspond to 287 new registrations of generic drugs, addressing 71 percent of Mexico's mortality causes. This resulted in an average price decrease of 60 percent in the private and public market, with the greatest reductions in medicines for diseases, which represent 50 percent of mortality in Mexico, namely diabetes, cardiovascular and oncology diseases, saving the government USD 2 billion in three years and offering additional treatment for 1.1 million Mexicans. We believe in 2016 we may even be able to save up to USD 4 billion. This has been very positive: since 2011 penetration of generics in Mexico has increased from 34 to 54 percent in terms of value and from 50 to 84 percent in terms of units, converting Mexico in the first market in the world for generics.

Let's talk about innovation now. We know that compared to more developed countries our portfolio of drugs is weak in terms of innovation, also because of the backlog the agency experienced until 2011. In 2010 COFEPRIS authorized only three new molecules and the average approval time for new molecules was five years. In 2011-2012 we implemented a policy to foster access of innovative drugs and started recognizing the work of other agencies, especially the EMA and the FDA. As a result, between March 2011 and August 2014 we have issued 133 new molecules, which account for 20 different therapeutic classes that represent 73 percent of the mortality causes in the Mexican population, namely chronic diseases. Moreover, we are now authorizing new drugs within 60 working days, which has helped transform Mexico into the global launch country for four new molecules (two for asthma and two for diabetes) and the dengue vaccine. If the regulatory agency is transparent, efficient and aligned with international best practices, results come.

In July 2012 Mexico was finally recognized as a National Regulatory Authority of Regional Reference by the Pan-American Health Organization (PAHO) and, more recently, as Functional Regulatory Agency for vaccines by the World Health Organization (WHO) for the 2014-2017 period. What do these recognitions mean for the Mexican pharmaceutical industry and how do they make the country more competitive at international level both from a manufacturing and country image perspective?

Besides improving access we decided to also develop an international agenda to obtain the recognition from the World Health Organization (WHO) and its Regional Office in the Americas, the Pan-American Health Organization (PAHO). We have been working with PAHO since summer 2011, receiving five in-person visits and obtaining the first certification in July 2012. As a result of this milestone we started being recognized by other countries and today are selling 70 generics to El Salvador, 50 generics to Ecuador, are opening Colombia and Chile, are starting to share GMP with an inward-looking market such as Brazil and are working with other agencies to expand access to other countries. A further goal of this recognition is to help increase exports of Mexican pharmaceutical companies. Traditionally Mexican companies have been mainly focusing on the local market, which is mirrored in a trade deficit for the pharmaceutical sector of USD 3 billion. However, today a fiercer competition and changes in the purchasing process of the government have significantly driven down prices, forcing companies to look abroad for additional market opportunities, which is very positive.

After PAHO we started working with the WHO to obtain the certification for vaccines, which is the more difficult process. Today we are the 28th agency in the world and this milestone will allow Mexico to generate new technology, because today we import 99 percent of our vaccines. The main goal of the WHO is to build local capacities. In fact, whereas in 1994 there were more than 60 manufacturers of vaccines, today we only have 40. Thanks to this recognition in 2015 Mexico is going to receive an investment of USD 45 million from Sanofi Aventis to build capacity to manufacture the influenza vaccine and export it to Latin America. And we are also receiving offers from companies in Korea and Europe to transfer technology. Today we are bringing new production capacities to Mexico because the country offers a competitive and attractive environment, not because we have a plant requirement as it was the case in the past.

What impact did all these initiatives have on Mexico’s macroeconomic and health indicators?

Thanks to all initiatives implemented, today we can boost better figures for many indicators we were worried about when we arrived in 2011. The main indicator was the percentage of public

budget destined to health invested in the purchase of medicines. While three years ago we were one of the last countries within the OECD, as a consequence of the strategies in place we decreased this percentage by two points, from 29 to 27 percent, moving Mexico up in the middle field. We aim at decreasing this indicator in five percentage-points, and this has been a terrific progress, as the indicator had not moved for 30 years. The other indicator, which improved is out-of-pocket expenditure in health. In 2010 it was 50 percent; today, using the last indicator of the World Bank, it's 44 percent — these were results we were looking for when we decided to revamp COFEPRIS.

Moreover, the timeframe to authorize a medicine in Mexico has decreased 80 percent in terms of regulatory burden and 98 percent in time. We authorize a new product in 60 working days and have implemented a very innovative procedure to lower the burden of the agency and of companies – authorized third-parties – which have allowed COFEPRIS to approve around 3,000 products within two years in less than 20 working days. Without the help of third-parties the average time would be 2.5 years. That's a considerable change in terms of opportunity cost, which has made us save more than USD 135 million.

We also deregulated medical devices with a risk assessment process – it was 1,600 in 2011 and we are going to soon issue a public decree to deregulate another 578, saving additional USD 204 million. We can say now that access has been strengthened, prices have come down, new products have entered the Mexican market making our portfolio much stronger and, although we are not a primary country for innovation, we are even moving in that direction.

Actually CANIFARMA wants to position Mexico as a hub for clinical research at a regional level and you recently signed an agreement with IMSS to open the institution to clinical trials. How will this agreement help Mexico become more attractive to invest in clinical research?

As a regulator we must generate better conditions to compete in a market as the one of clinical research, which is capital-intensive. The last figure we rely on is that global investment in clinical trials is USD 70 billion and only USD 200 million are invested in Mexico. One of the main aspects impacting investment decision in clinical trials is the approval timeframe. Mexico was not competitive, because we were authorizing trials in three months whereas other countries are doing so in 15 days. For this reason we issued the agreement with IMSS and the National Health Institutes. Today IMSS is working as a third party with COFEPRIS to authorize clinical trials and agreed in decreasing the approval time from a three to a one-month period.

Mexico offers optimal conditions to conduct clinical research, because if you get the approval for the Mexican market, thanks to the recognition by PAHO and WHO, you can directly access other markets in Latin America. Moreover, the country relies on a very heterogeneous population, including indigenous and mestizo people. We expect a considerable inflow of capital investment thanks to this achievement. The country manager of Novartis, Alexis Serlin, just announced an investment of USD 100 million in R&D activities in Mexico. I feel general managers in Mexico are receiving positive messages from their headquarters regarding the country. We expect 2015 to be very positive in terms of investment and are already preparing the approval of a new package of generics and new molecules in the first quarter, as we are going to continue along the same path.

Mexico is at the forefront with regard to regulation of biotech and biosimilar drugs and recently approved the Official Mexican Standard NOM 257 to provide additional regulatory framework to this category of products. How do you think the implementation of the NOM will impact the industry and when are we going to see the first biosimilars on the market?

Mexico was the first country in Latin America to include bio drugs in its legislation back in 2009. Biotech drugs are the medicine of the future, which will lead humanity to live in three-digit terms in twenty years. The policy of the Mexican government is to increase the use of bio drugs in Mexico. Today Mexicans consume USD 10 per year in bio drugs, while in developed countries it is USD 120 – this is a huge gap. We started generating consensus within the industry to work on the secondary regulation in 2011, when we issued the first regulation after the legal reform. We were able to send a very positive message, but there was an important pending item: biosimilars issued before 2009 – and none wanted to take the first step. In 2014 we had to renew innovative products and biosimilars, so time had come.

The first step of the authority was to inform the industry that we were going to work on a new regulation to, first of all, protect the Mexican consumer. We did not want to favor anyone but the consumer. We knew we had to issue a very clear rule regarding new products and biosimilars. This step is now a big issue in the US, where they have not approved any biosimilar yet, on the contrary of Europe, where they have done a very good job. We decided to issue a public and binding rule that states that we are not going to have biosimilar products in the Mexican market without clinical trials. Hence we incorporated a new scientific body to authorize the trials to be carried out for each product, considering the process for the innovative product but without repeating it as a whole– that would not be an access-friendly, but an obstructionist policy. We worked for one month – a very difficult month, I must admit – to generate consensus within the industry and decided that we

were going to open a two-year transitory period for the old biosimilar registrations to file clinical trials: if they don't by then, they are out of the market. The approval of new biosimilars will be submitted to this new scientific body on a case-by-case scenario and will be assigned the clinical trials to carry out. This has been a great achievement for Mexico and the publication of the NOM 257 in December was one of the most important items on my agenda for 2014 – and probably the one I was most afraid of – because I knew it was going to be a war. However, we generated consensus and I am happy to say that all stakeholders are happy.

We had to leave behind the short-term view, where everybody is only looking at the next government tender, to see the long term and big picture. This regulation will clear the way for the application of new innovative products and biosimilars and will attract investment. Innovative companies are working on biosimilars and we definitely have local companies that have the capacity to compete in this segment.

With the PAHO and WHO recognition in the pocket, what is COFEPRIS' next step and how would you like to see the commission by 2018?

We still have to lower times, become more efficient, be less costly, modernize the process to include IT and get involved in the technological agenda of the government, and offer better service on a daily basis. We receive more than 580,000 applications yearly, as we regulate 10 percent of Mexico's GDP. But I am very optimistic. I presented COFEPRIS' recent results and progress at the world summit of regulatory agencies in Beijing and we were selected to host the next agencies' summit in November 2015 – this is an indicator that Mexico has changed its image in front of the world. In the past, COFEPRIS did not participate in global events and conferences, and stakeholders were not listening to our voice. At the summit in November we are going to emphasize how modernizing regulatory agencies is key to strengthen access and offer better conditions to the consumer, who is the center of our policy, as well as to international investors.

What piece of advice would you give to investors looking at Mexico and the Mexican pharmaceutical sector?

Mexico is changing: the recent reforms ensure the country offers very different conditions for investment and the pharmaceutical industry features a very modern and transparent agency now. We have included an added value, which is untouchable, but very important: predictability and transparency. COFEPRIS was not offering this in the past and this is the worst scenario to attract investment. Today we are an agency, which provides services, as it is the case in any other developed country. Now investors know that they can get a new medicine approved within 60 and

clinical trials at IMSS within 30 days, that if they get a product approved in Mexico it will automatically enter 60 percent of South America's GDP (without Brazil) and that thanks to the WHO recognition we are going to expand vaccine manufacturing capacity to export to the world. And the results are tangible. In the past the industry was hardly growing one percent per year, while in five years it grew five percent and in 2013 seven percent. That's the evidence. 2014 was a difficult year, because we saw economic stagnation and the pharmaceutical market is related to the purchasing power of the population; however, if we align the industrial policy of the government with the industry we are going to see soon double-digit growth rates.

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