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Clinical research and access are the name of the game. The Executive Director of the association bringing together the most important research-based pharmaceutical companies discusses how the association has stepped up to partner up with the government and stakeholders to fight for the same objective and create a better health system in Mexico.

You have been appointed as Executive Director of AMIIF in May 2013. What has been your top priority since then?

When I joined AMIIF I realized over time the market had changed and so had the health system, but the association hadn't. Hence, I decided to make it my personal mission to move AMIIF from being a stand-alone organization which only represented the interests of its members to being one integrated in the healthcare sector and a meaningful actor able to sit down with the government to discuss how to improve the health system as a whole. In the past the association mainly focused on collaborating with Cofepris (the Federal Commission for the Protection against Sanitary Risk) and the IMPI (the Mexican Institute of Industrial Property) to lobby for its members' interests, as most activities were channeled through Canifarma, the Chamber of the industry. Interestingly enough, as soon as we started changing our role, people started listening to us and today we have a much better interaction with all stakeholders of the sector.

Everybody is always talking about making Mexico a more productive and competitive country, but what role does health play in this scenario? This is something AMIIF is actively concerned about – especially in the long-term. To discuss this last year at our annual meeting I invited industry experts such as vice minister Eduardo Gonzalez Pier, Hector Valle from IMS Health, José Alarcón from PwC and Luis de la Calle, an economist from the ITAM (Instituto Tecnológico Autónomo de México), among others. All of them brought up subjects we should start thinking of. For instance, most companies have orphan drugs and biologics in their pipeline; however, suppose the government had the funds to buy these medicines, what's the use of buying these products if we do not have the specialists to detect the problems? We also discussed about how big pharmacy chains are partnering up with hospitals and insurances, that only 7.6 percent of the population have private insurance coverage, far lower than in Chile, for example. Another hot topic is distribution: what is going to happen in the future after the bankruptcy of one of the top players and with other big new players coming in?

For this reason we decided to build up a document called 'AMIIF 2024', where we visualize how we see the health system in ten years and what things we do need to start working on today. It will take years to progress on some aspects, but if we never start we'll never get there. Now we have the overall strategy, an action plan and the to do's on which we can work on for the coming years – this is something we have never done before. The objective is to create a strong AMIIF relying on a long-term agenda, which we can fine-tune in progress depending on how the environment is changing.

Access is one of the main challenges research-driven companies face in Mexico. How does Mexico compare to other countries in the region?

We realized that if access was the most important problem, we needed to start addressing it as a stand-alone organization. In 2013 we commissioned IMS Health to conduct a study to better understand what the current status of drug access is in Mexico, what are the challenges companies and institutions face and how the country rates *vis-à-vis* other markets. The study showed that compared to countries with a similar level of development in the region, such as Brazil or Argentina – but even Poland and Turkey – with some few exceptions, Mexico rates very poorly, mainly because the process implies three steps: first Cofepris, then the General Health Council and finally the different public healthcare institutions, i.e. IMSS, ISSSTE and Seguro Popular. The whole procedure can take up to five years – way too long. Especially in the case of non-communicable diseases this time is unacceptable for patients and make the country lose competitiveness. Even though Mexico is the 11^{th} largest pharmaceutical market in the world, why should a chairman

consider it a priority if access is not granted? Today access is the name of the game – if we don't change this, investment will sink.

What is AMIIF doing to gain visibility at local and international levels?

Besides playing a more prominent role with the Mexican government and other stakeholders of the industry, today AMIIF is working much closer with other international associations, such as PhRMA (the Pharmaceutical Research and Manufacturers of America). In the past only 20 percent of our agenda was aligned with the one of the US based organizations. Now, within Latin America, our priorities are much more similar. Two years ago we were also accepted by IFPMA (the International Federation of Pharmaceutical Manufacturers & Associations) and for the first time this year we took part in a meeting in Geneva and will be part of the board at the annual meeting, which means we will be able to influence the agenda of the federation. This is a crucial step, as the IFPMA is very strong in front of the World Health Organization. Recently we also met with the OECD (the Organization for Economic Co-operation and Development), which plays a very important role in Mexico and where Mexico also stands in the spotlight, as the only Latin American country, along with Chile, member of the organization.

What do you think are the main challenges the Mexican health system is confronted with?

A recent move has been the implementation of consolidated purchasing among different institutions, which is supposed to help the government save nearly USD 340 million in 2015. However, the savings you achieve driving down prices should then be reinvested in health outcomes, one of which is access to innovative medicines. Unfortunately today the money saved does not go to health, but to support the existing inefficiencies of the system. Mexico only invests 6.2 percent of GDP in health, way below the OECD average of 9.5 percent and even below Argentina and Brazil. However, before allocating more resources to health, we first need to use the ones we have more effectively. That's why we are working on a project to understand where these inefficiencies are to be able to support the government improve them and then start fighting for more.

Some weeks ago AMIIF announced its agreement with IMSS to open the institution to clinical research for the pharmaceutical industry. What impact will this agreement have on investment in clinical research in Mexico?

Positioning Mexico as a hub for clinical research is one of AMIIF's strategic objectives. However, today the pharma industry is in a very different position with the government compared to other

sectors, which receive millions and millions of dollars of investment every year, as is the case of the automotive industry. At AMIIF we understood we need to find something, which is in line with the priorities of the government to attract FDI to the country. We need access, the government needs investment. How do we match that?

Based on prior experiences, I know that clinical research is heading towards other countries such as India and Korea because approval times in Mexico are too long for companies to wait. We recognize that Cofepris lead by Mikel Arriola and IMSS lead by José Antonio Gonzalez Anaya, have started taking steps to improve the administrative barriers of the past and, therefore, open the door to higher investments. I stressed this aspect with Mikel Arriola at Cofepris and then approached José Antonio Gonzalez Anaya and Dr. Javier Dávila at IMSS. Gonzalez Anaya is an economist, so he perfectly understood the importance of such a decision, taking in consideration the investment inflow it can bring to the institution. Everyone in the industry told me it would be impossible for IMSS to open to clinical research, but it happened because we found something, which was of mutual benefit for both parties.

So, what is going to be the next step on the agenda of AMIIF to position Mexico as a hub for clinical research and what benefits would clinical research bring to the country?

We recently signed an agreement with the Association of Clinical Research Organizations, which carries out 50 percent of the clinical research worldwide, to ensure international companies can bring clinical research to Mexico. In February 2015 we are going to bring together all the private and public stakeholders involved with clinical research, including CONACyT (the National Council for Science and Technology), FUNSALUD (the Mexican Health Foundation) and even people from the Mexican customs because we need their support to facilitate the import of samples. In 2013 Mexico received USD 160 million in investment for clinical research, while Argentina saw nearly USD 500 million despite the economic crisis – more than double. Why doesn’t the same amount of money get invested in Mexico? Possibly because the process is too slow. Every year USD 50 billion are invested in primary and secondary research globally. The question is: what percentage of that do we want to have in Mexico? Given the macroeconomic stability and strategic position we should get at least USD 500 million per year, which in a ten-year period would mean USD 5 billion investment – as much as the automotive industry.

The benefits of having more clinical research carried out in Mexico are several: from offering early treatment to patients with no cost to creating quality jobs; the average salary of a worker of the automotive industry is MXN$ 20,000, whereas in the pharmaceutical industry it is MXN$ 30,000 – 50 percent more. This confirms the pharmaceutical industry is a strategic sector to the economy.

Moreover, innovation does not only come from international companies members of AMIIF, but also from local companies. The agenda encompasses everyone and it can offer Mexico an interesting inflow of investment. Clinical research and access are the name of the game now. Without these, nothing can happen. The positive aspect is that although a lot still needs to be done, we are definitely on the right track.

What is your vision about the healthcare sector for the coming five years?

First and foremost, we need to find means of financing health. The industry is already open to finding alternative ways to the traditional ones, but before that the most important question we need to ask ourselves is: how can we more efficiently use the resources we already have? How do we improve administration and are more efficient? All this would definitely make a difference in the outcome of the patients. Second, we need more treatment options to be included in the national formulary, as we need to ensure patients get the best treatment options available on the market. It's not only about bringing down the price of drugs; research needs investment and without research there is no innovation. Diabetes is a very good example: to drive down costs this year Seguro Popular replaced the drugs included in its formulary with four-year old medicines – that does not make any sense, especially for a pathology which is so critical here in Mexico. Also, benefits on health cannot be seen on a year-on-year basis, but only in the long term.

We like to see Mexico moving towards universal health coverage and patients should definitely have the possibility to choose the institution where they want to be attended. However, it's still not clear how this is going to happen, as the benefits of patients affiliated to different institutions are very different. How is the government going to standardize them? In addition, if everyone can attend any institution, how can we avoid having people attending only one institution, namely the best one? Universal coverage is easier said than done – we want universal coverage but for all patients' needs, not only for basic treatments, such as paracetamol and aspirin.

Mexico is among the top economies in the world, the 11^{th} largest pharma market in the world and has a population of 120 million people. Yet, it is a country where the health system is very poor, so there is a lot of opportunity for improvement. The government just passed a number of reforms, which will have an impact on the Mexican economy in the long-term. No matter what happens, a lot of money will flow into Mexico. The potential is there – and this is said by a non-Mexican like me.

I am happy to say that today we have a totally different AMIIF, which has a voice and is integrated into a system. We are not the solution, but we are part of it, as we all are patients of the same health system and we have to fight all for a common cause – this is the common denominator.

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