Interview: Julio Sánchez y Tépoz – Federal Commissioner, Cofepris, Mexico



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Building on the continuous improvements of the Federal Commission for the Protection Against Sanitary Risk (Cofepris) over the last few years, its recently-appointed Federal Commissioner Julio Sánchez y Tépoz reveals his strategy to further strengthen and develop the Commission's processes and international leadership, and foster a more transparent, technical, efficient and global regulatory agency, which will tirelessly strive to improve the competitiveness of the pharmaceutical industry while never compromising its mission to increase the access of the Mexican population to a well-supplied and quality pharmaceutical market.

After holding key senior positions at Cofepris since you joined the Commission in 2011, you were appointed Federal Commissioner by Mexico's President Enrique Pena Nieto in March 2016. How has the Commission evolved between 2011 and the beginning of your tenure?

I indeed joined Cofepris as Chief of Staff in 2011, a year that marked the beginning of a crucial five-year transition era for the Commission, whose strategic objective was to build and strengthen a more disciplined Mexican pharmaceutical market. To fulfill this ambition, Cofepris had no choice but to revolutionize its market approval regulatory framework, which undoubtedly lagged way behind the highest international standards.

From 1920 to 2005, market authorizations in Mexico were not subject to any validity period, generating an unacceptable and unsustainable situation where laboratories could legally benefit from market authorizations issued decades ago – and that had never been reviewed since their release. In 2005, the Mexican government finally launched a deep and ambitious reform of the overall registration legislation, by introducing modern requirements in terms of bioequivalence, while a network of third-party laboratories was also set up to conduct these new bioequivalence tests in collaboration with Cofepris. Although this reform was introduced in 2005, the pharmaceutical sector was given a five-year period to prepare itself and develop these requirements that the new Mexican regulatory context was expecting, while the deadline to submit the new registration files was established to February 2010.

When the former Federal Commissioner Mikel Arriola and I joined Cofepris in 2011, our absolute priority was then to tackle the overwhelming backlog of around 20,000 applications that have been accumulating since this registration deadline. To do so, Cofepris implemented a strategic action plan to simplify, clarify, digitalize, and wisely deregulate registration processes, while a Center of Integral Services (CIS) dedicated to this Herculean task contributed to accelerating the elimination of the backlog and providing the pharmaceutical and investment communities with more certainty and predictability with regards to the registration process.

Five years later, I am particularly glad to announce this transition period is now well and truly over, as Cofepris recently managed to treat the very last registration files we still had to review. By putting an end to this resource-consuming backlog, Cofepris can now fully concentrate its efforts on new market authorizations, and bring another additional layer of certainty and efficiency to pharmaceutical companies. In parallel to this update effort, it must also be highlighted that Cofepris has also been able to align its registration timeline with the best international standards, as registrations for the Mexican market are now granted within 60 working days.

Cofepris’s recent achievements and progress in terms of market access processes have been unanimously praised, notably by the industry. As the new Federal Commissioner, what will be your strategic priorities to drive the Commission to new heights?

When I was appointed Federal Commissioner of Cofepris by President Enrique Peña Nieto, he notably established as a key responsibility of my mandate the further strengthening, improvement, and heightening of all the world-class processes that Cofepris has successfully implemented over the last five years, in order to both sustain the development of the pharmaceutical industry in Mexico and enhance the country’s international attractiveness.

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Since 2011, Cofepris's strategy has been primarily based on two main priorities: increasing the number of therapeutic options available to the Mexican population, and concentrating our efforts on the diseases that represent the largest share of mortality causes in our country. Regarding the first of these two priorities, Cofepris introduced a specific strategy in 2011 to massively facilitate the market access of generics, which aimed at significantly increasing patients' access to life-changing treatments while reducing the amount of out-of-pocket spending. With the registration of 491 new generics related to 47 different molecules over the last five years, Cofepris has been then able to generate total savings of more than USD 25 billion, while the average medicine cost decreased by 61 percent. Looking at innovators, Cofepris registered 216 new molecules over the last two years, while these cutting-edge treatments target 73 percent of the diseases currently threatening the lives of the Mexican population.

Building on these two fundamental priorities, we recently released our new Program 5/15 that will steer Cofepris toward its overarching objective to further improve its processes and increase its international recognition. This Program comprises 15 strategic initiatives articulated around five structural principles: improving transparency and ethics, always delivering the utmost technical expertise, further increasing our efficiency, bolstering industry competitiveness, and strengthening the regional and international leadership of Cofepris. By following these structural principles and implementing their related strategic initiatives, we want to ensure that the Commission deals with its partners with a heightened efficiency, predictability, and transparency.

Among these key principles, the positive impact of increasing transparency and access to information should not be overlooked. We deeply believe that providing the population and our partners with both a larger access to and a more comprehensive understanding of our regulations is a promising but still untapped incentive for better compliance with Cofepris's stringent processes. Inspired by the "open data" dynamic currently occurring in the most mature pharmaceutical markets, we also want to create a favorable regulatory framework that will bolster a larger involvement of external parties in the functioning of the Commission. In this endeavor, our current objective to accelerate the digitalization of at least 50 of our procedures will indisputably stand as a precious catalyst. To complete our transparency strategy, Cofepris will finally implement a comprehensive set of metrics to precisely monitor the impact and the outcomes of our 15 strategic initiatives.

Further improving Cofepris's efficiency is one of the key pillars of the Program 5/15, whereas other international regulatory agencies are probably less comfortable

displaying such a self-improvement philosophy. Why is endlessly improving the efficiency of Cofepris so important to you?

In May 2014, the World Health Assembly released its resolution 67.20, which was negotiated for at least a year by fifteen of the most respected regulatory agencies in the world. This resolution clearly stipulates that “effective regulatory systems are an essential component of [the] health system’s strengthening and contribution to better public outcomes”. On the other hand, this resolution also highlights that if a country is not able to swiftly authorize treatments that are already available in many other countries or create powerful-enough incentives to attract research and development investments, then this agency becomes nothing more than a regulatory barrier that prevents its population from accessing highly-needed medical products.

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We definitely don’t kid ourselves: there is an uncontestable causal relationship linking an efficient sanitary agency with better access of our population to the pharmaceutical market. As a result, we consider that without an efficient and transparent sanitary authority, our country cannot improve the health situation of its population.

This WHA resolution is of the utmost importance; as it is the first time in at least twenty years that regulatory agencies acknowledge that that their inefficiencies ultimately restrain the access of their population to life-saving treatments. Beyond this recognition, it also embodies a real change of mindset, and population can expect that regulatory agencies will no longer exclusively see themselves as a technical filter holding a superior scientific expertise, which sometimes sufficed to justify years-long approval processes.

Cofepris will never compromise nor neglect its technical expertise, which also stands as one of our five key principles that constitute the core of our Program 5/15. Cofepris’s philosophy however is to deliver this sheer scientific expertise as rapidly and as efficiently as possible, as we strive to operate as a real driver of our country’s health system, and not only as a market entry filter.

Fostering clinical research investment is high on the agenda of all Mexican healthcare stakeholders. What could be the contribution of Cofepris in this regard, while protocol approvals continue to be described as too time-consuming in comparison to international standards by some voices in the industry?

We currently see that most of the research and development investments remain concentrated in the countries that boast the best research infrastructures, but also the most advanced patent protection and regulatory frameworks. These three parameters precisely explain why we deeply believe Mexico holds such a promising potential in terms of attracting clinical research investments. First of all, companies can rely on Cofepris's recognition as a National Regulatory Authority of Regional Reference by the Pan-American Health Organization (PAHO) and as a Functional Regulatory Agency for vaccines by the World Health Organization (WHO), while we are also joining the Pharmaceutical Inspection Convention Scheme (PIC/S). Beside the strength of its regulatory agency, Mexico also proudly displays more than 20 National Institutes pushing forward the research boundary in a great variety of therapeutic areas and disciplines, while these Institutes are not only ranked among the best in Latin America, but also from a global standpoint. Finally, in Mexico, investigators can access almost 85 million patients through IMSS and ISSSTE social security networks.

Looking at protocol approvals, COFEPRIS, IMSS and the National Health Institutes issued a promising agreement in 2014 to reduce approval timelines and increase Mexico's competitiveness in this regard. As a result, National Health Institutes can now operate as third parties conducting pre-assessments of clinical trial protocols and enhancing a close collaboration with Cofepris during the approval process. While National Health Institutes' experts have always been in charge of adapting and developing clinical trial protocols, there was no real communication until 2014 between the Institutes and Cofepris, whose responsibility is to ultimately approve the protocol. Obviously, this absence of interaction was dramatically expending approval timelines, which stands as one of the most prominent parameters taken into account by pharmaceutical companies when they decide to conduct clinical research in a country.

The first outcomes of this new pre-approval system are utterly promising, as on one of the first projects to test this procedure we managed to reduce approval timelines from 60 to 14 working days. We however know that we still need to deepen our efforts in this regard, and further increasing clinical trials' speed of approval is one of the 15 action items of our strategic Program 5/15.

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As part of the clinical research strategy that Cofepris will release for the Commission's 15th anniversary in July 2016, we also want to improve National Health Institutes' pre-approval efficiency. Clinical trials protocols currently need to be pre-approved by several committees within a given Institute, which is obviously extremely time-consuming. We then want to set up

committees specifically dedicated to clinical research within each National Health Institute that will vertically supervise the entire approval process and directly liaise with Cofepris.

Finally, besides working on improving the regulatory framework surrounding clinical research, Cofepris will also leverage its international exposure to promote our country's untapped attractiveness and competitiveness in this field, while our universities and research centers clearly hold the scientific expertise to meet the needs of the international community.

Cofepris is about to join the Pharmaceutical Inspection Convention Scheme (PIC/S). To what extent do you expect this important milestone to transform Cofepris's processes and the Mexican industry?

Cofepris's entry into the PIC/S will be officially effective from July 4th 2016. This crucial achievement is not a mere coincidence, as the Commission has been intensively and extensively preparing this entry over the last two years. This time was absolutely necessary to ensure our internal processes and human resources' skills are perfectly aligned with the expectations and standards of other PIC/S members, while PIC/S' cooperative modus operandi is based on the mutual trust and reliance on the inspection expertise of all members that belong to the organization.

When applying for entry into PIC/S, Cofepris's capacity to fully understand and properly evaluate all manufacturing processes of a pharmaceutical facility was meticulously scrutinized by other PIC/S members. Cofepris is joining 46 other countries that have also successfully passed their entry test; making Mexico the second Latin American country to join this prestigious group. As a result, the pharmaceutical industry implanted in Mexico can expect a tremendous decrease in inspection costs, as complying with any PIC/S country's inspection will be simultaneously recognized by all other members. The entry of Mexico into the PIC/S is undoubtedly positively revolutionizing the entire business approach of all pharmaceutical manufacturers implanted in Mexico, and–by reducing inspection and then manufacturing cost–we hope to further nurture the investment flow to our country.

What are the strategic objectives for Cofepris's soon to be opened Center of Excellence?

As for clinical research investments, knowledge and expertise are unequally scattered all around the globe, as international research hubs boasting cutting-edge infrastructures and concentrating the most important financial resources also gather within their walls the largest share of this global knowledge. If, as a country, we want to become even more attractive and efficient, we know that knowledge is absolutely paramount. As a result, one of the essential mandates of this new Center of Excellence will be to benchmark, identify, incorporate, and train our human resources to the best

practices that are developed and implanted by the most respected regulatory agencies in the world.

By cooperating with other international agencies, I want to establish a strong communication and expertise channel that will link Cofepris with the most mature and advanced countries, while the Center will also be officially recognized as a regulatory center of excellence by the WHO. To further stimulate knowledge transfer, we will ensure that international experts in all relevant matters are continuously invited to Mexico to nurture a world-class scientific debate in regulatory affairs, but also provide our people with first-hand training. In this regard, we are intensively tightening research and training alliances both within Mexico and on an international basis to stimulate the expertise flow that will soon reach Cofepris's Center of Excellence, as it is set to officially open its doors during the second semester of 2016. Finally, we really want to build a holistic and cross-sector knowledge approach, by inviting both the pharmaceutical and chemical scientific fields to contribute to this promising initiative as well as the private sector.

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Mexico and Cofepris have already been playing a very prominent role in the Latin American region in terms of establishing good regulatory practices and training our counterparts. By enriching this robust and long-standing expertise with the direct input of the most respected experts of the world, we realistically expect to reach a higher level of expertise and soon be in the position to provide training to other parts of the world.

From a mid-term perspective, what is your vision for the pharmaceutical sector in Mexico?

First of all, the pharmaceutical sector in Mexico should soon be recognized as a strategic sector for the Mexican economy. The Ministry of Economy has already showed some support for this exciting idea, which renders me particularly optimistic regarding the positive evolution of the pharmaceutical industry in our country. The pharmaceutical sector in Mexico has displayed robust and continuous growth in recent years, while the regulatory requirements and compliance of the sector has been indisputably improving as well, which can be largely attributable to Cofepris's endless commitment to improving its regulations and processes. In the upcoming years, Cofepris will continue to invest to heighten the certainty and excellence of its processes, develop our

international leadership, and tirelessly expand our sheer contribution to the sector’s growth and to the promising development of the Mexican economy.

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