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As 2016 turned the corner into a new year, macroeconomic uncertainty kept the world – and the global business community – on tenterhooks. The Mexican health industry cast a wary eye on events north of the border that were impacting the local exchange rate while also focusing treatment efforts on obesity and diabetes, which continued to top the country's major health concerns. Considered as epidemics by the government, steps are being taken to eradicate these diseases in the country, especially through prevention. However, universal access to health, a key to promoting prevention in an increasingly aging population that is not accustomed to continuous medical checkups, remains an illusive ideal in the face of a fractured Mexican health system and the large number of people who continue to work informally, which complicates their access to a system marked by budget cuts. In this context, collaboration between the public and private sectors is vital for improving quality of life.

In the private sector, global economic uncertainty, and the election of US President Donald Trump, led large pharmaceutical companies to begin 2017 with some misgivings about peso volatility versus the two major currencies: the dollar and the euro, although initial fears faded as stability returned to the domestic currency. In fact, most continue to report growth and show a commitment to the development of health in Mexico through investments in areas such as clinical research, an area in which the country aspires to become a referent.

The health sector, which represents around 6 percent of the country's GDP, continues to be a strategic industry for Mexico, a country blessed by an ideal geographical location, neighbor to the US and gateway to Latin America for many companies, and a diverse population. Mexico Health Review 2017 offers key insight into the challenges and the opportunities the industry continues to face, providing top-shelf interviews, analyses, insights and infographics. Mexico Health Review 2017 is essential to understanding the state of the health industry in Mexico today and for the path ahead.



A 121 MILLION PEOPLE CHALLENGE

JOSÉ NARRO Minister of Health of Mexico

Q: In 2016, you declared diabetes and obesity a crisis. However, FUNSALUD's José Campillo has said that rates are leveling off. Is this a success?

A: I cannot yet say that we have had success because the population is not fully conscious about the dimension of the problem. Secondly, although there has been a deceleration of the death rate, there is no decline. The number of deaths due to diabetes multiplied by about seven times between 1980 and 2015, from around 14,600 in 1980 to 98,500 in 2015. In the 21st century so far, there have been 1.1 million Mexican deaths directly due to diabetes. This is a grave problem. We must ensure that the measures that appear to be effective are maintained. We also must act to protect young children and teenagers. For this reason, in May 2017 we began the *Salud en tu Escuela* (Health in your School) program, which will send doctors to over 1,700 primary and middle schools to talk about key health topics.

Q: How do you control the various media campaigns aimed at children and what is the key to promoting healthier habits?

A: There is increased control over advertising campaigns that target children, such as for candy, food and drinks. I agree with President Peña Nieto that health begins at home. It begins with topics such as hygiene, nutrition and lifestyle. We need to work with parents because they must understand that a child of four should not have food portions equal to that of the father. School is the secondmost important place where children develop good or bad health habits. The Ministry of Health and the Ministry of Public Education have an excellent relationship and the Education Reform will enable us to further improve this.

Q: How effective have public information campaigns been?

A: There is an important link between public campaigns and health but we have to keep pushing. There have been great marketing campaigns to raise social awareness in this country. Going back several decades, there were intelligent, wonderful campaigns that were strong for their time concerning reproductive health, family planning and nutrition. We are continuing this tradition and in 2017 our focus is on diabetes. Young people are generally healthy, although they must look after themselves. The elderly are another issue altogether: the idea of being ill frightens them. They prefer not to go for check-ups for fear some condition will be discovered, but prevention is the name of the game. We have to bet on prevention and this has to be cultivated from a young age. We used to think that a chubby child was happy and healthy but they must have a healthy weight. We must all act.

Q: Life expectancy is increasing. What challenges are arising for healthcare as a result?

A: Mexico's population, like many around the world, is going through a demographic transition. Population pyramids have changed from 20 years ago when there was a strong base of young people. Now, the number of old people is increasing. Forty-five years ago, the median age was 17.8. Now, it is 27, so we can say that the population is maturing. Children and the elderly are dependents and there are just over five million people aged over 70 but that figure will increase to over 17 million in 2050. Today, a regular infection can be cured while chronic, nontransmissible. nonparasitic infections can be controlled. Health is a process, not a state. Health ranges from the complete state of physical and mental wellbeing as defined by the WHO, to a second before death, when health is basically lost. In between there are many states, some better than others. If people see health this way, prevention can be put in place. We want to promote education so that more people can take control of their health. We must begin to build processes for healthy aging.

Q: Pollution is an ongoing issue in Mexico that directly impacts health. What is the Ministry of Health doing in this regard?

A: We have serious problems in Mexico City, but both local and federal governments are taking action. We now have much better ways of measuring pollution levels and better instruments to measure the impact that polluting particles have. Some actions taken include the restriction of vehicles and industrial activity, which limit mobility. The Environmental Commission of the Metropolis (CAMe) is a coordinating mechanism that includes local, state and federal levels of government. President Peña Nieto requested that the commission includes the Ministry of Health.

Q: What challenges arise in ensuring the continuity of projects after the 2018 presidential elections?

A: There has been much done in terms of health over the past few years. Under the current government, maternal mortality has fallen by over 18 percent, infant mortality has decreased by 6 percent, mortality due to accidents has also dropped and the frequency of dengue fever has been reduced by two-thirds. In addition, there have been many new medicines incorporated into the healthcare system. Since 1948, the change has been phenomenal. Infant mortality has decreased by over 90 percent. Back then, 132 of every 1,000 children died before their first birthday. Now, the rate is 12 of every 1,000. This country has been lucky with public policy in several programs, otherwise we would not have been able to achieve what we have. A clear example is vaccination. For over 40 years we have been dedicated to vaccinating the population. There is no rubella or congenital rubella in Mexico, we have controlled diphtheria and tetanus and neonatal tetanus has been eliminated.

Since 1974, there has been a program for family planning and now for reproductive health. Thanks to these programs, Mexico has 121 million inhabitants instead of over 150 million. There has been an extremely successful campaign running since the 1980s to protect children against diseases caused by dehydration. I trust that even with political changes, current health policies will be maintained.

Q: What is the Ministry of Health doing to spread its message on reproductive health to all of Mexico, including rural areas?

A: We have to make the problems visible or they will not be solved. We are providing information and education and we must also provide services. In the rural environment, we have two mechanisms to spread health awareness, the first being state governments. Programs are defined nationally but implemented by the states.

We must also ensure the service is available. IMSS-Prospera, for example, has services for teenagers in rural and indigenous environments. We must guarantee that services to provide condoms, pills and other anticontraceptive methods such as salpingo-ophorectomy or a vasectomy can be offered. Some are more adequate for young people than others, but for someone that has already had many children, one of these methods may be more appropriate. We must guarantee access to information and to these services for all so that people can make their own, informed decisions.

Q: To what extent will the Ministry of Health be working on reforming medical degrees for young doctors?

A: We are working on a revision at the moment and in early May we attended the ANFEM assembly. The number of schools, programs and students has increased greatly. The number of specialists, however, has not increased greatly, because there is neither need nor space for a greater number to train as specialists. We have not valued the role of the general practitioner. If there are no positions for general doctors, how can they be hired? There are organizational aspects of health that must be reviewed, so we must be clear. The reality of rural Mexico, where we need doctors, is not attractive to them. We are speaking only of doctors but there are many other professions in healthcare. The topic of human resources is obviously central and so we are working on this.

Q: What are your priorities for 2017?

A: Diabetes is one of our highest priorities, but it is difficult to tell which is the most important because there are many, such as cancer and heart disease. When speaking of priorities, I often speak of diabetes because it generates the most deaths as a single cause. Cardiovascular disease may cause more deaths when grouped together, but the causes are many and can be split into three main groups: heart attacks, hypertension and others.

Another great issue is pregnancy in girls and teenagers. Children of 10-14 years old are having babies. There were 400,000 births in 2015 and almost one in every five births is to a teenage mother. The government has implemented a national strategy aimed at preventing teenage pregnancies, which are often unwanted and unplanned. The consequences are many: families are ruptured, studies are abandoned, the young girl often has to work and often the father of the baby disappears and leaves her with the child or children. We have been working with different structures since January 2015 on this strategy, which is being coordinated by the National Council of Population (CONAPO). Prevention and education are fundamental.

Regarding cancer, the Chamber of Deputies and the Chamber of Senators in the Mexican Congress has approved the establishment of the National Register of Cancer, which will be a powerful tool for delineating public policies on how to allocate resources and where the focus should be. Cancer is the third highest cause of death in Mexico.

Dr. José Narro is a surgeon from the Faculty of Medicine at UNAM, with a master's in communitarian medicine from the University of Birmingham, England. Narro was head of UNAM from 2007 to 2015 and in 2016 was named Minister of Health



DYNAMIC CHANGES PROPEL MEXICO TO WORLD STAGE

JULIO SÁNCHEZ Y TÉPOZ

Commissioner of COFEPRIS

Q: What are the most important advances COFEPRIS has made in the past year?

A: We have made great strides on ethics and transparency, we have become an institution that is much closer to citizens and we have put 10 catalogues of open data at their disposal. These are registers of licenses, permissions and other types of information that was previously requested of us. We have also installed a telephone service that receives 16,000 calls per month.

COFEPRIS regularly removes patents from groups of medicines to allow for the production of generics. In 2016, we released Group #14 because in February 2016 there was an issue with influenza and the active substance to treat it, oseltamivir, was only produced by one laboratory and manufactured in Switzerland. In May 2016, we liberated Group #14 and there are now three generics available for oseltamivir. In total, 37 active substances have been liberated through our generics strategy, producing 491 generics, which represent MX\$25 billion (US\$1.4 billion) in savings while an extra two million people can be treated thanks to these savings. In 2017, we will continue with this strategy and more than 40 new molecule authorizations will be announced. Last year, Mexico was named Vice President of the International Coalition of Medicines Regulatory Authorities (ICMRA), an international association that unites the 14 most important regulatory agencies, for two years. We are a leader due to our generics strategy, innovation, reduced processing times for protocols and special pathways for administrative forms, which can now be obtained in 15 days instead of two years as it was five years ago.

Q: How is COFEPRIS working on bringing more knowledge to Mexico?

A: One of the most important themes internationally is the creation of the COFEPRIS Center of Excellence. We began

The Federal Commission for the Protection against Sanitary Risks (COFEPRIS) is a regulating authority responsible for 44 cents of every peso spent by Mexican households, 9.8 percent of GDP and 10.9 percent of foreign trade working on this idea around two years ago with the aim of closing the knowledge gap because knowledge is not shared in the pharmaceutical sector. Those that have money, like large companies with the capacities to invest in R&D, do so in specific areas. But there is a gigantic difference between the amount of R&D that goes on in developed countries compared to less developed economies. A first gap is created here. A second gap occurs because of the difference in technical knowledge. They want to protect knowledge and for this reason it is not transmitted. Secondly, knowledge only reaches those countries that collaborate and that offer assurances.

As an example, it is doubtful that Brazilian research centers share their knowledge quickly, efficiently and transparently with Nigeria because standards are asymmetrical. We need to improve the flow so that every country can benefit quickly and efficiently from knowledge. We aim to contribute to reducing these gaps as much as possible through a center of excellence. This was an idea of the WHO and APEC and they should compile information and generate joint public and private actions so that knowledge can be shared. Our center has several research and training projects underway in areas in which it is difficult to find an expert. There are few other centers but those that exist are linked. Japan, the US and Brazil each have one.

Q: According to ProMéxico, Mexico carries out only 1 percent of global clinical trials. How will you boost this number?

A: In January 2017, we signed an agreement to promote clinical research that simplifies processes and integrates them. To meet all requirements and obtain all permits used to take 365 days but we are reducing this to 45 days. Our goal is to triple the investment in clinical research in Mexico and we hope to see US\$600 million over the next two years, up from under US\$200 million. An agreement has been reached with IMSS and ISSSTE will soon join the program. We are working on another agreement with the national health institutions and with UNAM. This will no doubt happen by the end of 2017.

Q: How do you evaluate which areas should be the main focus for sanitary authorities?

A: We evaluate which conditions have the greatest prevalence in Mexico through reports such as ENSANUT, which was released in late 2016 and covers NCDs. We use these results to assign resources and generate biotechnology to solve the most prevalent health problems in Mexico. We were the first country in the world to authorize the dengue vaccine and we are in the process of establishing a protocol for its application.

Q: What results have you seen and what do you expect from the new pharmacovigilance NOM?

A: NOM-220, which was published in March 2017, represents a paradigm shift. It implies that many more players are responsible for pharmacovigilance: the patient, the doctor, the laboratory, the pharmacy and the distributor. This change generates more reports that help COFEPRIS to provide a more punctual and strategic follow-up on the effects and quality of these medicines. With few reports, all we can do is check manufacturing plants but with pharmacovigilance we have more information and this propels change.

Q: What process does the commission use to identify areas of overregulation and resolve them?

A: We will be working on the third phase of deregulation of medical devices and we are considering removing regulation from 10 percent of the devices currently on the market, perhaps more. This has been presented in international forums where we have been identified as innovators.

We base our decision on analyses of sanitary risks. Scientific advances in medical devices means that the sanitary risks are lowered or eliminated as faster and more effective solutions are discovered. The sanitary risk of technology in medical treatment and medical devices changes depending on technological advances and the same happens with medicine. There are combinations that do not generate increased secondary side-effects.

Another element is that we realize that there are delayed administrative processes. We are digitalizing processes to avoid unnecessary costs in transport, paperwork and time. This is part of COFEPRIS Digital, implemented in December 2016, which has taken 99 forms and administrative processes online. With the extra 50 that we are adding, we will save 600 tons of paper in a year. All these simplified processes will help bring us closer to citizens and to provide a much more agile service. In addition to being based on reviews, we also perform an audit biyearly, one of which is focused on our internal quality-management system.

Q: What is the single most important area COFEPRIS will be focusing on in 2017?

A: My mandate is to protect public health. If I had one dream for 2017 it would be for the population to be closer to us, to consult us, to give us a chance and to call us. It would be wonderful if before citizens took a decision of any kind, they first looked after themselves and consulted us. To ensure this message reaches all of Mexico, we have an amazing program called Seis Pasos de la Salud (Six Steps of Health) that is translated into 17 indigenous languages. It will see a new component with the Ministry of Public Education through which we will soon reach schools.

COFEPRIS RESULTS

152.4 million

approved and analyzed

the National System of

to ensure their quality in

vaccines

Vaccination

innovators

+250

74%

US

cheaper

than in the

(2012 - 2016)

COFEPRIS REGULATES





8% of aross domestic product





+500 generics

2014

2,242 6,307 deregulated new devices registrations

21

areas

covered

therapeutic

+6,300

medical

devices

1,998,202

additional patients treated

61% price reduction

71% of mortality causes covered

Source: COFEPRIS

2012

% of out-of-pocket

expenditure of total

health spending

42

41 .

40



SIMPLIFIED REGISTRATION BOOSTS MEXICO PHARMA MARKET

RAFAEL GUAL Director General of CANIFARMA

Q: How has the pharmaceutical industry evolved in the past two years?

A: I think it has evolved well and regulation has continued to advance. The structure of registration has been simplified so that time targets set out in the law are met for any process involving the sanitary authorities. This is an important advance that has allowed the pharmaceutical industry to be more competitive in Mexico and in international markets. Being recognized as a regulatory agency has allowed COFEPRIS to be much more agile in registering products in Central and South America.

In terms of R&D, we have authorized a series of third parties to be much faster in clinical authorizations, which will allow Mexico to become a center of clinical research. In economic terms, the market has maintained 3-4 percent yearly growth over the past decade, a rate that will probably not increase as the market is mature and grows in line with the population. The export market has grown in double digits and will continue to do so thanks to COFEPRIS, which has been recognized as a national regulatory reference agency in Central and South America. Companies have this advantage in addition to GMPs. Thanks to economies of scale, the Mexican economy is more competitive and can export to these other regions.

Q: How has the new pharmacovigilance NOM affected companies and how easy or difficult is it for companies to adapt to it?

A: The new norm offers patients security and provides faster product registration. If a drug does not have any reports of major adverse effects caused by the pharmacovigilance NOM, then registration can be renewed quickly. The NOM also commits other parties such as doctors and patients to reporting adverse effects. It is no longer the sole responsibility of the industry. It will cost the industry more but we think we will reach an agreement with the authorities on what is necessary and what is desirable.

Q: How is CANIFARMA helping the industry homogenize its regulation with the FDA and EMA?

A: They are already homogenized. There is not much difference between the regulation that exists in Mexico and

those countries. Existing regulations and laws in Mexico are not insufficient; all that is lacking is evidence that they are being followed. Having them written is one thing, ensuring compliance is another. The recognition from the WHO and PAHO of Mexico in terms of vaccines provides certainty that the role is being fulfilled. COFEPRIS has to report evidence of verifications and certainty of reports. Tracking may be different in the US and Europe, but we are still missing an agreement with the FDA and the EMA on a bi-dimensional code that can be applied worldwide.

Q: What advantages does Mexico present for clinical research, other than its large population?

A: In Mexico, most R&D is carried out in private centers. The main issue is researchers being paid to carry out the studies. There is a promising environment in IMSS to incentivize clinical research in Mexico, sponsored by the industry as there were issues with IP. This has been changed. Previously, if IMSS found a second use then the IP belonged to the agency. But an agreement has been reached so that the IP does indeed belong to the industry sponsoring the research. The advantage is that there are 50 million patients in IMSS with varying stages of disease because in Mexico there is no culture of prevention, which means diseases are available for study at advanced stages that may be hard to find in other countries.

Q: What other steps are being taken to boost clinical research in Mexico?

A: IMSS, COFEPRIS and CANIFARMA are on the verge of signing a contract to facilitate the path to clinical research. During our CANIFARMA Awards 2016 we announced that a research fair would be held during which companies will be able to have direct contact with the companies that won the awards in 2016 and 2015, to allow the research to be taken to market. Julio Sánchez, Commissioner of COFEPRIS, has announced he will support this with a certificate and the research will be followed by COFEPRIS from the beginning. This will contribute to further improving the relationship with the industry. Brazil and Argentina are Mexico's biggest competitors in clinical research in the region. The fact that we have a large number of patients to register in a clinical trial aids our competitiveness worldwide. Mexico can increase patient numbers greatly if we make the most of IMSS. Brazil and Argentina are more agile.

Q: What are the biggest challenges in the human pharma industry?

A: We need to become an important center for clinical research because its potential is underused and we have to consolidate COFEPRIS' recognition to open new markets for the industry. There is great quality in the products manufactured in Mexico and they are competitive. In addition, we need to continue consolidating regulations. I would add access, which is one of the main issues in the country, including new technologies which, despite having a greater cost, can bring increased benefits to the population. We need to facilitate this access in IMSS, ISSSTE, CSG and the National Formulary and I personally believe that opening clinical research in IMSS will facilitate the inclusion of new technologies, because having done the trials will shed light on the benefits they can provide in comparison to current medicine.

Q: What are the biggest challenges in the veterinary pharmaceutical industry?

A: They are extremely different. First, because there is no animal social-security system and there is no worry of incorporating new technologies. Challenges are more related to competitivity and access to international markets, as the market has been conservative in worrying only about the Mexican market. There are many multinationals here that are growing. The main issue is the topic of pure salts in food mixes. If a farmer administers pure salts instead of the correct medication it will cause problems. There are also issues with antibiotic resistance due to residue in food. There is no pure clenbuterol medicine for example, only medicine that contains traces of it. Sadly, we do not have the muscle in Mexico to create a regulation around this.

Q: What role do you play in investigations such as that of COFECE?

A: We give COFECE the information it requests but we do not have a proactive role. We clarify the panorama of the pharma industry. There are topics such as prices that are forbidden for discussion during any of the chamber's meetings. In every act it says that it is forbidden to exchange commercial information. This legally binds the chamber and its members to avoid these issues, so we provide requested information. We are asked for example why all expired patented products do not have generic alternatives. It may not be commercially viable, it may be a difficult product to create or the ingredient source may be unique, and this is a worldwide condition. If the patented product is interesting enough for a generic to exist, it will.

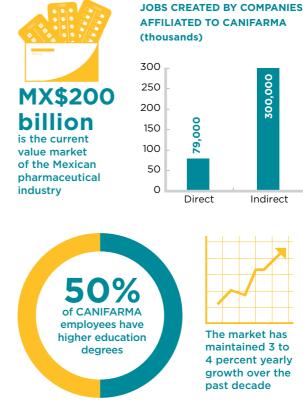
Q: What area will you focus on in the future?

A: Previously, a product had to be registered every five years. We are working on a scheme that will allow changes in a product to be recorded before its five years are up, as the current process created bottlenecks at the end of five years. Many products are modified slightly and this will allow companies to reregister it as soon as it happens.

CANIFARMA ACHEIVEMENTS



Created the CANIFARMA Award to encourage research on the most significant causes of mortality



Sources: COFEPRIS, CANIFARMA

The National Chamber of the Pharmaceutical Industry (CANIFARMA) works toward developing the industry in Mexico with three main objectives: sanitary regulation, research and innovation and economic development and industry policies



COLLABORATE TO INNOVATE

CRISTÓBAL THOMPSON Executive Director of AMILE

Q: Research, development and innovation are AMIIF's top three core values. Which is the most important for 2017?

A: Innovation is always at the top of the agenda. It is the reason why we exist and we have been working on this. The goal of AMIIF's 2024 vision, its midterm plan for innovation, is to contribute to improving Mexico's productivity and competitiveness through pharmaceutical innovation. That is our key goal. As President Peña Nieto has said, we are experiencing a renaissance for innovation. For example, hepatitis C products, which have a 95 percent rate of cure, have just been approved for inclusion in the public health system, which is an incredible breakthrough. There are new treatments in HIV and patients are living almost as long as nonpatients and with minimum side-effects. There are also new innovations in cancer treatments.

The objective of the agreement is to increase annual investment in clinical research from around US\$250 million to above US\$600 million

One issue for pharmaceutical innovation is how to finance it. We sat down with IMSS and now we have three teams working with the institution to establish innovative access models based on patient health outcomes. The project began between February and March 2017. Our first group is working on the analysis of the cost to the system and the

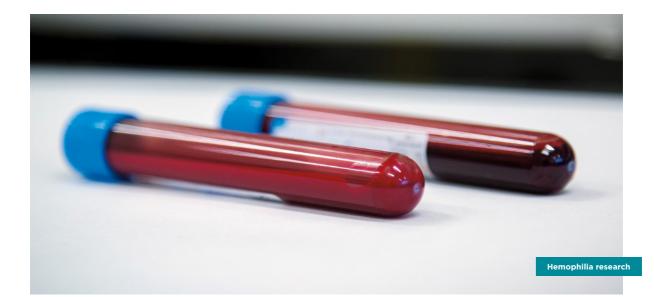
The Mexican Association of Pharmaceutical Research Industries (AMIIF) encompasses over 40 of the leading pharmaceutical and biotechnological research companies in Mexico and aims to promote innovation in the health sector epidemiological impact of the main therapeutic areas to be prioritized in this project (potentially: diabetes, cancer and cardio-vascular diseases). The objective of the second group is to analyze new performance indicators and criteria to align patients and institutional needs in said therapeutic areas. The third group is a legal team discussing how and when the government could be able to implement innovative access models, aligned with the proper legal framework. Financial and legal experts and doctors also attend these meetings.

We are also looking at how we can bring in more resources via clinical research. In January 2017, there was an agreement made between all parties with President Peña Nieto present. Its objective is to increase investment in the sector from around US\$250 million to above US\$600 million. A meeting in early May 2017 brought together COFEPRIS, IMSS, ISSSTE, the decentralized institutions, ProMéxico, the Ministry of Economy, SAT, Customs and the industry. We will have monthly meetings to provide updates on each area, understanding that by the end of 2017 we should have a better process for getting protocols approved to bolster the amount of funds coming into Mexico.

A pillar of increasing access to innovation is to make understood its potential impact on productivity and competitiveness. Last year, we presented a study with the automotive industry in Guanajuato, which tried to show the impact of lost productivity on a sector. In the case of the auto industry, the impact of lost value was around 7.3 percent of the industry's value, of which 1.3 percent was absenteeism and 6 percent was due to presenteeism. We are close to the big employers such as the Business Coordinating Council (CCE), COPARMEX and CONCAMIN to make sure that everyone has a voice in making sure our health system, social security and Seguro Popular deliver a better job.

Q: How much awareness remains to be raised among governors?

A: At the beginning of May 2017, Dr. Narro, Minister of Health, attended our board meeting for the first time. He said that health and education are the two highest social equalizers. At the federal level, we have done a great job and awareness is



higher than it was three years ago. Having said this, budgets were cut last year, showing that although there is awareness, this does not correspond to action yet.

At the governor's level, we have to improve awareness. Investment must be holistic: people must be healthy and with a good level of education. They must have infrastructure and public services, but there must be a good health system too. We have been asked by the Ministry of Economy to undertake another study like the one we did in Guanajuato, a state that is growing at 6-7 percent per year. If employment continues to grow but the health system does not keep pace, there will be a bottleneck, a problem of too much success too quickly but with a gap in these kinds of public services for workers and their families. Again, investment usually goes to places with good infrastructure. If this is not addressed, there will be limitations in economic development.

In May 2017, Mikel Arriola, Director General of the IMSS, announced tests in Nuevo Leon in which IMSS would follow up on company employees to see who was at high risk and to begin taking preventive measures early on. The more information we can give the government, the better.

Access to innovation is low, as only 10 percent of innovative medicines approved by COFEPRIS are in the public health institutions. Early diagnosis and secondary prevention is much less expensive than waiting five years for patients to get out of control. Then, by the time you give them innovation, the cost will still be too high. In Guanajuato, we asked companies what they were given from the government: land and tax incentives. They did not think to ask about health. Getting the big employers onboard is a big part of the agenda and this will resonate when we hold events. Investment will come but states have to look at how to maximize that investment.

Q: A renegotiation of NAFTA is likely. What will AMIIF's top priorities be?

A: We hear a different version every day, from modernization of NAFTA, which is something we want and that the government is clear about in its position, to removing it completely. Although we do not know what will happen, we are prepared for various scenarios. The chairman of GE was here in May 2017. He made it clear that NAFTA was very good and he said that the big employers need to start speaking up. I think they will start coming out and saying that yes there are areas for improvement but overall commerce is highly integrated. How can it be disintegrated? Impossible. The companies here have been present for many years and they will not go back. It the treaty collapses, we will not see major issues, unless a tax is imposed on imported products, but we do not think that will happen. Overall, NAFTA has been beneficial for all three countries and I am sure renegotiation will center on optimization and on areas that did not exist when it began, such as e-commerce.

Q: How does the Accelerated Access initiative decided in the WEF in Davos this year complement AMIIF's 2024 vision?

A: This is a huge initiative. Top pharmaceutical companies are joining together to develop a common framework that will help patients and countries battling NCDs in low and middle income countries. The industry is talking about looking for a full, holistic approach to the health system, trying to find ways to make overall improvements and enabling medicines to patients. For example, 300 billion units of medicine are donated every year to Africa, but it lacks distribution infrastructure. What we are implementing in Mexico is already a step ahead of what my colleagues in other countries tell me.

Q: What will AMIIF focus on in 2017?

A: Our main focus is how we can grant greater access to more patients. We will be finalizing steps to attract more investment to clinical research, to keep working with COFEPRIS to continue improving timings and processes for approvals of new molecules and finally to maintain the current standards of IP protection.



DIABETES AND OBESITY: HEALTHCARE PRIORITIES

JOSÉ CAMPILLO Executive President of FUNSALUD

Q: In 2016, FUNSALUD established diabetes, breast cancer, obesity and mental illnesses as priorities. Have these changed in 2017?

A: Our priorities remain the same because these conditions have a high incidence and involve a great cost to society and the country's finances. At the end of 2016, Minister of Health José Narro declared diabetes a health emergency. It was an atypical statement because there was intention to take drastic action but only to emphasize that diabetes is a serious national public health problem. At the end of 2016, the ENSANUT survey was released. It measures obesity, overweight and diabetes prevalence among the Mexican population. In some segments, which vary between urban and rural communities, rates begin to stagnate rather than continue shooting upward. However, there is another hypothesis: we are reaching saturation levels where things cannot get any worse. In 2017, emphasis should be placed on the prevention of diabetes and its complications. Data from this survey show there has been a 175 percent increase in diabetic foot amputations.

Q: Are citizens more aware now than before of this type of complication?

A: I do not think the population has that information and if it does, it has not resulted in a lifestyle change. This is the main challenge of a problem that is multifactorial and that depends not only on food but on life habits. A change in the population's mentality is required.

Q: The IMSS estimates that in the next 35 years the number of patients with diabetes in the country will double. Do you agree?

A: There are many possibilities. In addition to the 6.5 million diabetics diagnosed it is thought there is almost the same number undiagnosed, so the logical thing is for

The Mexican Foundation for Health (FUNSALUD) is a private institution that aims to contribute to the improvement of health in Mexico by being a reference point for the discussion of the health agenda prevalence to increase. FUNSALUD has corroborated this number with its own studies. In 2013, we estimated that the cost of diabetes would be MX\$362 billion (US\$20.1 billion) per year or 2.3 percent of national GDP. This figure will continue to grow and there may come a time when the public sector does not have the economic, technical and human resources capacity to deal with this tsunami.

Q: Which countries can Mexico look to for a way to attack this epidemic?

A: Chile and Costa Rica are seeing good results, although the comparison in terms of population is different. European countries like the UK also have good models. However, we are seeing the problem in all countries, which is due to urbanization, lifestyle changes and consumption habits. I think Mexico, the country with the highest obesity rate after the US, could be the place to experiment with immediate action. One action should be to increase clinical research, especially for economic reasons. It is a gigantic global market in which Mexico does not even reach 0.1 percent and needs to be improved. Mikel Arriola, Director of IMSS, is convinced of this. The industry is also ready and COFEPRIS is at the best moment in its history, with great international recognition. Mexico can be an important crucible to start doing scientific research on diabetes that provides us a favorable cost/benefit ratio. In 2017, it would be desirable for the Ministry of Health to take the lead to carry out a concerted policy with the Ministry of Economy and the Presidency of the Republic. Ties with the industry exist thanks to the great work carried out by COFEPRIS.

Q: What has changed in the last 12 months in relation to conditions such as breast cancer or mental illness?

A: The capacity of care for these diseases has increased. However, budgetary or political considerations have meant that these are no longer priorities for the federal government. In terms of breast cancer, much progress has been made in perception and detection. The pharmaceutical industry is shielded from any political aggression by the current president of the US and the Ministry of Health is at the core of the solution. By



improving the health of the working population, great savings will be made.

Q: Universal access to health is a goal of FUNSALUD. How is the Ministry of Health working toward that goal?

A: Universality is not a utopia but an obligation. Family wealth should not be affected by healthcare. It is an inalienable universal right that cannot be postponed. The conditions of the country in 2017, and perhaps for the next five years, are going to be very adverse, so we have to rethink proposals to reinterpret the reality and be precise in our aspirations. The most important part is to ensure prevention and first-level care. One of the main problems is that the model we followed was seen from the perspective of the disease and not from health; we have been curing and not conserving health. We need a policy of prevention.

Q: How will budget cuts affect the goal of achieving universal access to health?

A: Recently, an agreement for the protection of the family economy was signed and four strategies were proposed but the health sector, which should be the beginning of everything, appears in none of them. It is an element that is systematically forgotten but without a healthy population there can be no healthy economy. The priority for 2017 should be to place health at the heart of any strategy, which is not easy.

Q: To what extent are doctor's consultancies in pharmacies a solution or an externalization of the problem of health access?

A: Their existence tells us many things. It is a phenomenon that appeared spontaneously to solve problems that should have been resolved by the government. However, waiting times are shorter and care is personalized, inexpensive and close. They are a tool that depends on us to make them favorable or harmful. There are about 15,000 offices and they must be taken into account. Now, ethical principles have to be established as well as a register of patients and greater communication, among other elements. FUNSALUD wants to make a substantive proposal in this regard in 2017 in which we will try to bring together government, academia and industry to conclude a document in 2018. Emphasis should be placed on the first level of care.



SIMULTANEOUS TARGETS, POSITIVE RESULTS

MARCO NAVARRETE-PRIDA

Deputy Director of Health Services for PEMEX

Q: What are PEMEX's health priorities for its beneficiaries in 2017?

A: As a healthcare provider, we have to focus on simultaneous targets. However, we began as a medical services company, so labor health is our main concern. We have doctors at every work site to deliver preventive care and promote health, hygiene, risk detection and to evaluate the compatibility of employees with the jobs they do. For example, some employees work 35-60 meters above a platform or land. They cannot suffer from vertigo, have the flu or a high BMI because that would be risking their life. At PEMEX Health Services we are further ahead in health services than other industries such as automotive, pharmaceutical and aerospace. Our priority is to have our workers operating under the best conditions possible. Instead of building more hospitals, we want to focus our efforts on promoting preventive care. In fact, PEMEX has 41 health centers, including 10 first-class clinics, 24 hospitals and 168 preventive centers of labor health. Our hospitals are operating on average at 70 percent capacity.

Q: What challenges does PEMEX face in retaining workers when faced with many new market entrants?

A: We work closely with the union and it is committed to our focus on prevention and health promotion. The paternalistic scheme in which the state or PEMEX provides everything to a passive beneficiary does not work. There should be a commitment from the employees, too. To this end, we have integrated a health bonus, which is given to workers with a BMI of less than 25 or for those who lose 10 kilos in a year. If they comply they get the bonus.

Q: What relationship do you have with other public healthcare institutions?

A: President Peña Nieto and Minister Narro are working on the universalization of health services, which means

Petroleros Méxicanos (PEMEX) is a state-created oil and gas company and is the largest company in Mexico. It runs its own healthcare system for its workers, which is also one of the largest in the country that each institution has to be open to providing and receiving support from other institutions. We have an agreement with all the National Institutes of Health and we hire subrogated services in some other locations. We have partnerships with health institutions in Sonora, Aguascalientes, Tamaulipas and Veracruz. In cases of industrial emergencies, we receive a lot of support from IMSS. We also have an agreement with the Ministry of Health to fumigate work areas to prevent vector-borne diseases and we provide them with fuel for their trucks.

Q: How did you manage the delegation of part of your services to a private insurance company?

A: From the beginning, we have hired private services to support those PEMEX locations that lack a health facility but which have active workers, or a total 104,000 beneficiaries. Two years ago, PEMEX's supply department designed a strategy to have one health administrator instead of 95 providers. Unfortunately, the results were disappointing and we are now in the process of returning to our previous system.

Q: What opportunities do you offer students who want to do medical residencies in PEMEX hospitals? Which specialties are available to them?

A: Through PEMEX Health Services's resident program we have trained high-quality and specialized professionals. We have schools at Hospital Central Sur de Alta Especialidad and Hospital Central Norte in Azcapotzalco, Mexico City; Hospital Regional Ciudad Madero, Tamaulipas and Hospital Regional de Salamanca, Guanajuato. There are 18 specialty and five subspecialty programs available for 388 students in the country.##

Q: What is PEMEX's contribution to Mexico's growing clinical research industry?

A: We perform clinical trials to see which type of drugs and medical devices are best. In fact, two years ago we launched our molecular biology laboratory at the Hospital Central Sur de Alta Especialidad in Mexico City, where we are carrying out bacterial studies and soon will start a genetic study of the PEMEX population.



CAMPAIGNING FOR BETTER HEALTH

JOSÉ REYES Director General of ISSSTE

Q: In addition to health services, ISSSTE works on prevention through public awareness campaigns. Which areas are key targets?

A: We have a number of ongoing campaigns. One such campaign relates to addiction prevention, particularly smoking, and targets young people through courses, conferences, personnel training, graphic information and social media. We are also drafting several campaigns against overweight and obesity and their related conditions, which have a profound effect on quality of life and on the federal budget. Twenty percent of ISSSTE's health-allocated funds were used to raise awareness of diabetes, overweight and obesity, hypertension and cervicouterine, breast, prostate and colon cancer. ISSSTE's annual budget amounts to MX\$45 billion (US\$2.5 billion) and we are spending MX\$10 billion (US\$555 million) or more just on these diseases.

Among specific programs, the Salud en tu Escuela (Health in your School) campaign is focused on young people and on the children of beneficiaries who suffer from overweight and obesity. This is a joint effort between players in the public health and educational spheres, such as the Ministry of Public Education (SEP) and the National Education Workers' Union (SNTE). Integrating teachers as health promoters and developing permanent awareness and physical exercise campaigns are key objectives that will enable ISSSTE to evaluate the results at each school in the program. The effort will include physicians, nurses and some students from ISSSTE's School of Nutrition and Dietetics. The ISSSTE en tu Dependencia (ISSSTE in your District) program is focused on monitoring the health of employees. ISSSTE has identified about 570,000 diabetics among its beneficiaries. Another campaign targets breast cancer across public health institutions. We integrated 25 new mammography machines into our facilities and we are finishing a new diagnosis center in one of our hospitals. Between 2016 and 2018. ISSSTE's goal is to triple the number of mammographies from between 110,000 and 115,000 to 350,000. ISSSTE is raising awareness among women between 25 and 69 years old. Although we have reduced the prevalence of cervicouterine cancer and the related mortality rate, the same cannot be said for breast cancer. We named February Men's Health Month because

men are less likely to visit a physician than women: 63 percent of first-time doctor's appointments are women.

Q: On the business side, what are the advantages of building hospitals through PPP schemes?

A: ISSSTE has an infrastructure program and fiscal resources but, due to budget adjustments, we have had to vary our financing to continue building and expanding hospitals and clinics. We needed to migrate to a new scheme involving the private sector. ISSSTE invested over MX\$4 billion (US\$222 million) last year in building and expanding a number of clinics and hospitals. We have analyzed several new hospital projects in Tampico, Acapulco, Oaxaca and Mexico City and there are also some requests for new hospitals in San Luis Potosi and Sonora. There is a PPP hospital being built in Merida and three others to be tendered: Mexico City-Tlahuac, Villahermosa and Tepic. We estimate that in this federal government administration's remaining time, investments from PPP schemes could total about MX\$14 billion (US\$777 million).

Q: What criteria helps ISSSTE to decide where a new hospital or clinic will be built?

A: The location of beneficiaries and public health infrastructure are the key criteria. The Ministry of Health, ISSSTE and IMSS have developed a strategy that prevents duplication, so if there is an IMSS hospital in a community with an ISSSTE clinic and someone at the latter needs surgery, hemodynamics or cardiovascular services, these will be subrogated to the IMSS hospital. Services will also be subrogated from IMSS to ISSSTE, which does not mean implementing a universalization program but exchanging services and prioritizing cities and states according to the demand for health services and the existing public infrastructure. All public-sector agencies need to maintain a close relationship. We also have collaboration and serviceexchange schemes between both public and private entities.

The Institute of Safety and Social Services for State Workers (ISSSTE) is the second largest of Mexico's public health institutions, providing health and social services to almost 13 million government workers



MEXICAN COST-REDUCING TECHNIQUES TO HIT EUROPE

JAIME CERVANTES CEO of Grupo Vitalmex

Q: Which of your products differentiate you from your competition?

A: The first product we offer to public institutions are personalized solutions based on specific health needs and challenges. This product has worked well in Mexico because it offers flexibility for public healthcare providers. We are working with three imaging clinics in the north and south regions of Mexico, where we are looking to improve access to diagnoses for local communities. The second product we offer is integrated services, a pay-per-procedure strategy for elective surgeries and procedures. The hospital or clinic pays us for completed procedures, which means the customer does not need to invest in fixed assets and inventories to offer health services. It is a win-win situation because we profit through the correct management of economies of scale in the procurement of medical devices, high logistics efficiency and high productivity with our latest-generation equipment. Our third product is inventory management. We are experts in transporting medical items and devices. Because of the volume that we manage in 210 hospitals in the public sector, we offer this service to private hospitals as well with significant reductions in variable costs and permanent availability of materials. Our fourth product is the management of health centers and hospitals. Our vision focuses on three segments: infrastructure development for the public health system, working with insurance companies to reduce the cost of premiums and satisfying the needs of patients at the bottom of the socioeconomic pyramid through micro-credits.

Q: What are your expansion plans over the next several years?

A: Our plans detail three strategic lines of development and growth from two main sources. The first line is to maintain business with our public sector clients. The main products we offer to public institutions are personalized solutions designed to address the national health coverage challenge.

Vitalmex is a consultant that helps clients improve their business model. It has three main lines of business: imaging diagnostics, surgery and the treatment of chronic diseases. Originally established in Mexico, it has now set its sights abroad In parallel, we are extending our capabilities to the private market through focused investments.

Another growth strategy we are analyzing is the development of our own clinics and hospitals with a focus on the treatment of noncommunicable diseases and minimally invasive surgery. The primary causes of death worldwide are cardiovascular diseases, followed by cancer. Vitalmex is an expert in treating these ailments and that is where our development plans also focus. This is a high-growth area in healthcare and we are carrying out market research to analyze possibilities in that segment.

Finally, we believe there are opportunities to export our business model. We are successful in Mexico and the healthcare challenges that we face and the given services are similar in many countries.

Q: Why expand to Europe when many exalt the opportunities to be found in Mexico?

A: I believe that our business model is replicable in many countries because healthcare challenges and trends are similar to those in Mexico. We already have a great deal of knowledge of integrated services and believe there are many opportunities to create efficiencies for existing hospitals in other countries. What we offer is a proven model to help them reduce their capital investment costs, increase their productivity, optimize their installed capacity and improve quality indicators, as well as treatment techniques.

Mexico is a market with a great deal of potential. However, there are also many opportunities abroad, in both emerging and mature markets. In places like Germany, Switzerland, the UK, France, the US and Austria, the cost of medical devices and disposables is increasingly high. In those countries, hospitals and insurance companies are looking to reduce costs and we believe that our integrated solutions are an attractive and proven way to do so. For example, the owner of 12 hospitals in Switzerland invited us to evaluate their operations. It turned out that we could reduce their costs by around 15 percent through integrated services.

DISPARITY A CHALLENGE IN PUBLIC-PRIVATE COOPERATION



ALEJANDRO ALFONSO

CEO of ABC Medical Center

Q: How is ABC Medical Center cooperating with the public sector?

A: The healthcare situation in Mexico demands private hospitals work together with the government because it is not economically viable for the government to meet healthcare service demands by itself. The key is to find the right way to make this happen to avoid the perverse incentives in the private and public sectors that pollute association. ABC Medical Center has been working with public healthcare through Seguro Popular and by offering occasional services to other government institutions. As a not-for-profit organization, we can afford to treat patients below cost and this is important because helping those who do not have enough resources is a part of our founder's legacy. The challenge is to determine the price the government can pay for these services and how economically and clinically efficient we can be as a private hospital when providing this aid. If there are no clear rules about quality and affordability, we may find ourselves in a situation wherein we can no longer help the population.

I am concerned about the decision to create general hospitals without a structured business plan. The word "general" by itself might be counterproductive because it suggests the hospital can treat any manner of illness and it does not highlight the public's true needs. A general hospital is not built based on a study of the population and popular diseases. For its construction, rent is paid to a private company, which fulfils its construction and installation contract, at which point the government takes operational control of that hospital. The little money this general hospital receives is spent paying the private company and there is not enough left to treat patients, which indebts the government. Instead, to improve existing services there should be an inventory of the country's hospital capacity and an analysis of how they could be better used. There are empty surgical theaters at certain times of the day in private hospitals that could be used by the lines of people in public hospitals.

Q: What is the thrust of ABC Medical's relationship with Seguro Popular?

A: Our relationship is strong but there are certain rules that keep us from offering it more products and services. For

every MX\$1 it pays us, we have to give MX\$0.19 to the government. Seguro Popular does not pay VAT but as a private hospital we are not exempt.

Another issue is the difficulty of selling services to Seguro Popular. Hospitals have to undergo several timeconsuming registration processes so the patient stream is initially slow. Seguro Popular was created with the theory that "money will follow the patient," so everywhere he or she goes there will be a budget to pay for the service. The actual situation is that the federal government gives each entity a budget targeted as money for Seguro Popular but a given entity may not necessarily be equipped with the services specific patients need. Therefore, there is a large migration of patients to Mexico City, where large hospitals, specialized clinics and good service can be found. When those patients arrive at the hospitals in the city, the center's administrator must find a way of covering patient costs because the state to which the patient belongs will not pay.

The truth is that money does not follow the patient because security systems for patient care in Mexico are sectored. With IMSS coverage, a patient can only go to IMSS facilities. Mexico operates a vertical system, so there are many patients for whom there is no budget. We see teenagers with high-risk pregnancies camping outside hospitals, waiting for care without a place to sleep, and most of these are helped by civil organizations.

Q: What approach could help solve the health system's current situation?

A: The solution is not easy and is not short term. First, we have to discuss which healthcare model we want to follow with the participation of many social agents. Once the model is established, we can decide our course of action.

ABC Medical Center is a private institution in Mexico City that offers treatment in the fields of oncology, neurology, transplants, OB-GYN, pediatrics, traumatology, preventive medicine and nutrition



INNOVATION A KEY TO PATIENT-CENTRIC CARE

FÉLIX SCOTT

Director General and Country Chair of Sanofi

Q: How does Sanofi approach patient-centric care in terms of products and therapies?

A: We are convinced that products by themselves are not enough. A holistic approach that includes pathology and solutions is required. It is essential to always take into account that beyond every product there is a patient. This is very important in healthcare, especially with therapies for chronic diseases. Sanofi has a broad portfolio and we are Mexico's number one pharmaceutical company in number of drugs. Chronic diseases are a social concern that are related to lifestyle, which is why we are redefining treatment.

Q: How much of Sanofi's R&D is conducted in Mexico?

A: We have a clinical research unit here that does research for Mexico and for some countries in the Latin American region. Mexico plays an important role in the implementation of Sanofi's clinical studies and is top-of-mind when it comes to allocating those studies. The country is among Sanofi's top five emerging economies and the Mexico branch ranks 10th among all global subsidiaries. Today, there are more than 35 active phase III and IV studies in Mexico. The country is one of Sanofi's most important clinical research units for emerging countries. We also have a program with the Aspen Institute and UNAM that is focused on native research, in which we sponsor research by local professionals who are venturing into projects focused on local needs.

Q: What pharma-economic solutions can you offer the market to provide more access to innovative therapies?

A: We developed a monoclonal antibody to treat cholesterol. This innovative therapy is more efficient than statins, which are the usual treatment provided by public institutions. Patients treated with statins are still prone to heart attacks, which in the end will be more expensive than any therapy. We are seeing this purchasing behavior start to change and we hope that decisions begin to target innovation. We can

Sanofi is a pharmaceutical group founded in 2004 after the merger of Sanofi-Sythelabó and Aventis. It is the world's third-largest pharmaceutical group and a leader in research in Mexico with over 35 active studies provide patients with a solution that can return them to an active lifestyle, especially those with conditions like multiple sclerosis. An oral therapy might be cheaper than our solution but it causes more hospitalizations and is more expensive over the course of a lifetime, while an innovative solution will result in expenditures for only three years. We have patients who were treated with our therapies 20 years ago and have not needed further treatments, although we continue to follow their progress and symptoms. There is an opening in the healthcare system to include more innovative drugs but we must accelerate the process for chronic diseases. Many of our products are already included in the public system but we need to provide access to high-tech products and treatments.

Q: How does Sanofi provide healthcare professionals with access to innovation and how does that talent benefit the company?

A: We offer a continuous education platform (PAEC) that is the result of a cooperation agreement between Sanofi and the Ministry of Health. Many Ministry of Health doctors are certified in the programs offered through this platform. For example, we offer certification for treating diabetes. We do not promote any of our brands through this platform because our main objective is to increase the number of trained doctors. We have certified around 16,000 doctors through PAEC in just three years. There are about 14,500 family doctors actively participating in the platform. We want to continue developing talent in Mexico and we want to increase our team's diversity. We are interested in nurturing talent in indigenous communities and we have developed a scholarship that helps train that talent. We also want to export talent from Mexico to Sanofi's global subsidiaries.

Q: What are Sanofi's priorities in Mexico?

A: We want to continue redefining health for Mexican patients, which means making the most of all the opportunities we have to promote significant change in patient health through the private or public sectors with innovation in drugs, training, support for doctors and through scientific research. For us it is important to bring Sanofi's global innovation to Mexico.



DIVERSE PORTFOLIO ENSURES GROWTH

RODRIGO PUGA

President and Country Manager of Pfizer Mexico

Q: Generic medicines are becoming more popular in Mexico and innovator patents are expiring. What is Pfizer's strategy to deal with this?

A: Access to health services is an important challenge. Mexico spends 6 percent of its GDP on health, the lowest expenditure of all OECD member countries, as others spend an average of 9 percent on health. Pfizer has launched its first biosimilar, a product for rheumatoid arthritis that IMSS is providing, and we are developing biosimilar versions of its five most-sold biotech medicines to be launched over the next four or five years. Pfizer's strategy is to participate in attractive segments and to target growth above the market rate. To achieve that goal, we must compete in innovation. The company has 90 projects globally and over US\$7 billion invested in R&D. It also has a business base of patent-expired drugs that are still successful due to our quality prestige. We are successful in emerging markets because, although regulations have improved, physicians and patients do not trust all generics. However, we have also launched a generics line, a segment in which Pfizer enjoys an average growth of 35 to 40 percent annually.

Q: On what pathologies is your pipeline going to focus?

A: The five main areas in which Pfizer is working are oncology, central nervous system, cardiovascular, rare diseases and biosimilar drugs. It is hard to say where the best results will be, because out of every 100 projects that start in the clinical phase, only one will reach the market. We invest about US\$7-8 billion per year and launch one or two new products per year.

Q: What is Pfizer's strategy to sell innovative drugs to the Mexican public sector?

A: The arthritis biotech product Pfizer introduced to IMSS already existed and we developed the biosimilar version. In innovators, the challenge is showing public health institutions the cost/effectiveness ratio of products, starting with the CSG, IMSS, ISSSTE and decentralized agencies. A new drug has a patent with 15 years of exclusivity from when the molecule is discovered. It takes eight to 10 years to gain approval and introduce the drug into a market and in Mexico four to five years for the product to be available to the public sector.

Q: What is Pfizer's approach to personalized medicine?

A: Pfizer already has some personalized products in the market; for example, our therapy for patients with ALK-positive non-small cell lung cancer. In immunotherapy, especially oncology, the objective is to strengthen the immune system to combat cancer. Most cancer treatments use biological and chemical compounds but this Pfizer treatment could help the immune system target tumor cells directly. In oncology, it is difficult to decide when to launch a product because it does not follow the same cycle as other products. Pfizer's acquisition of Medivation will enable us to strengthen our clinical research into prostate, breast and blood cancer.

Q: What are Pfizer Mexico's priorities for the rest of 2017 and 2018?

A: Along with Brazil, Pfizer Mexico is a priority subsidiary. Pfizer Mexico's commercial objective is growing above the market growth of 5 percent. The company will continue launching innovative medicines, biosimilars and high-quality generics. We want to continue working closely with AMIIF to demonstrate that investing in health is one of the best investments in terms of economic impact. We also want to work on innovative access strategies.

Pfizer Mexico will also continue innovating in clinical research. With 121 million inhabitants, excellent professionals and a decent level of infrastructure, there should be much more clinical research in Mexico. This does not happen because administrative processes and institutions delay procedures more than they should. The company has over 400 research centers in Mexico, although it is still an incipient process. According to AMIIF, Mexico could be looking at a US\$500 million investment in clinical research in the near future. Pfizer will invest US\$16 million in Mexico in research in 2017.

Pfizer is a US-based global pharmaceutical company present in over 180 countries with a strong research focus. It works in a variety of therapeutic areas including oncology, cardiovascular health, vaccines, ophthalmology and infectious diseases



CHALLENGES IN THE FACE OF A CHANGING MARKET

KAREL FUCIKOVSKY

Director General of Pierre Fabre Médicament LATAM

Q: What challenges do transnational companies face in the Mexican market?

A: Overall, market access poses challenges and question marks for all players. We are a heavily regulated industry and even more so due to our internal compliance with government policies. In Mexico and Latin America, our time to market for drugs is getting slower and our capability as a transnational company versus local players at times cannot be compared.

Registration for market authorization for new products is one of the hardest hurdles to comply with for many companies, especially for innovative drugs and therapies, even considering that the authorities have simplified processes and timeframes.

Unfortunately, we have examples of novel drugs that have been in the registration process for almost six years and there is still no answer as to when market authorization will be granted. This obviously generates financial and business forecasting issues for us, plus big questions from our partners in Europe trying to understand the situation.

Q: How are your sales divided between the government and private sector?

A: Of our overall business, 45 percent relies on government sales, consolidated purchases from the main health institutions and some decentralized organizations that are also within our business scope. This 45 percent is divided between two branches: oncological drugs for lung and breast cancer and Fabroven[®], indicated for patients with venous insufficiency.

The retail market drives 55 percent of our business, with our franchise products in women's health. Navelbine Oral and Fabroven[®] are our top-selling and most prescribed products in the Mexican market. They will continue to grow in the institutional segments as well as in the retail market because they have strong active promotion, investment and medical and scientific fundamentals.

Q: How have public sector budget cuts affected your business over the past year?

A: The pharmaceutical industry in Mexico has been impacted in different ways from the budget cuts and constraints in the public health sector. In our case, the impact has lacked strength because our marketed products, such as Navelbine Oral, are targeted at patients with lung cancer and breast cancer, both considered top national health concerns regarding treatment priorities in Mexico.

We are fully aware that the operational and financial strategy of the authorities should be to lower the fixed costs of institutions, which is the reason there is a strong movement in Mexico to substitute innovative drugs with generic forms.

Fortunately, our generic exposure is still limited in our various therapeutic segments. We agree absolutely on the need of generics in the market to make medicine more accessible to the whole population because we fully understand that a healthy population creates a more productive country. But there should be an examination of whether transnational and national companies are competing on a level playing field, because that is not the case in some locations.

Q: What new products has Pierre Fabre launched in the past year?

A: Through a joint venture effort with Ferring Pharmaceuticals, we obtained a license agreement and distribution rights for Lysteda, a prescription product indicated for patients with excessive menstrual bleeding conditions. Lysteda is a key product that strongly contributes to enhancing our women's health portfolio.

Lysteda has been on the market for over a year and a half and has seen great acceptance among our medical community and patients. This development represents an interesting approach for us because we are marketing it as a training product for physicians and use the same traditional sales channels as wholesalers do.

We also produce an orphan drug called Busilvex, used to support bone marrow transplants. This is a one-of-a-kind

product in Mexico, as it is the only drug available in IV form. Busilvex has been on the market for five and a half years and even though it does not represent large volumes for our business it does makes a big difference in the way procedures are managed by professionals, especially when considering that patients need an exact quantity of product present in their bodies to be prepared for a procedure.

Busilvex is not at the core of our business strategy, but surely represents an opportunity to support our oncology franchise development. I do not think the company will migrate to an orphan drugs business model. It will be much more oriented toward oncology, women's health and dermatology.

Q: What difficulties have you faced getting an orphan drug registered in Mexico?

A: Orphan drugs have different registration processes and "go to market" possibilities than conventional medicines. Perhaps the registration pathway for orphan drugs could provide faster market entry but the medication must still meet all regulatory requirements.

Q: What challenges do transnational companies face in the Mexican market?

A: Overall, market access poses challenges and question marks for all players, be they national or transnational companies, public or private. The pharmaceutical sector is a heavily regulated industry, and even more so due to internal compliance policies, which differ on a company to company basis. In Mexico and Latin America, our time to market for drugs is slowing and our ability to compete as a transnational company versus local players at times cannot be compared.

Registration for market authorization for new products is one of the hardest regulatory hurdles to comply with for many companies, especially in regards to innovative drugs and therapies, even considering that there have been huge improvements from our authorities and that we are on the right path to simplifying processes and time frames.

Unfortunately, we have novel drugs that have been in the registration process for almost six years and still have no definite answer as to when the marketing authorization will be granted. This obviously generates financial and business forecasting issues for us, plus big questions from our partners in Europe trying to understand our authorities' processes and timeframes as we have invested a lot of money in those products.

Q: How can your company sustain growth while relying only on mature products?

A: Worldwide, mature products are our bread and butter. They allow us to continue investing in R&D globally and to power ourselves in joint ventures locally.

As an example of this, Pierre Fabre has signed a worldwide agreement with Array Pharma, a big pharmaceutical company, for the co-investment and development of two molecules for melanoma and colon cancer.

Q: What are your expectations for the next five years?

A: We will continue to focus on our portfolio management strategy, based on specific therapeutic areas: stay strong in oncology, be a fundamental player in the women's health market and grow in dermatology and oral care.

Mature products allow us to continue investing in R&D globally and to power ourselves in joint ventures locally



We will continue to enhance partnerships worldwide and as an example of this, five months ago, we signed a licensing and distribution deal with Grupo Biotoscana, a strong and respected pharmaceutical company in Latin America, for Navelbine Oral and our full oncology portfolio.

In our five-year strategic plan, we will focus on portfolio management and a solid arm of our development will be looking for strategic alliances. We have seen in Mexico, Argentina and Brazil that many transnational companies are suffering due to divestment strategies on their mature portfolios. They have focused on highend technology and biotechnology products without considering access barriers and the low rates of payers. Now, some of these big companies are realizing they are losing out but lack the resources to revive their mature products that still have strong brand equity. We have grasped these opportunities and started partnering with some companies. We have been working with Janssen for the past three years on part of its gynecology line, with positive results for both companies.

Pierre Fabre is the third largest French pharmaceutical laboratory. It has two main lines of business: Pierre Fabre Médicament, which focuses on the pharmaceutical sector, and Pierre Fabre Dermo-Cosmetics, related to dermatology and cosmetology



PRIZE STIMULATES R&D INNOVATION IN BIOTECH, NANOTECH

EFRÉN OCAMPO

President and Executive Director of Grupo Neolpharma

Q: What areas has Grupo Neolpharma targeted in the last 12 months?

A: We have just completed construction of the plant area in which we will be producing nanotechnology. We are moving our production capacity for pilot batches of biotechnology products there and we are also increasing investment so that all pilot production is carried out under GMP conditions.

Q: What is Grupo Neolpharma and CINVESTAV's prize for innovation in bio-nanotechnology?

A: Biotechnology and nanotechnology are two lines in which we are interested in stimulating research. The prize was linked to pharmacology but it is now more open as it has enabled the creation of new materials. The invitation to participate is open to all the institutions and professionals working in those disciplines and the prize is MX\$300,000 (US\$16,666). Half of the award is to reward the researcher and the other half is to fund the continuity of the winning project. The purpose of the prize is to create new talent, provide exposure and increase the diffusion of these kinds of scientific proposals. We are approaching 2016's winning researcher to ask for his help capsulating some drugs we want to deliver to the limbic part of the brain.

Q: What new heights would nanotechnology enable the pharmaceutical industry to reach?

A: Nanotechnology is a technique that can be used to produce medicine. If a medicine that causes unwanted side-effects is made using nanotechnology, those effects can be reduced instead of damaging the stomach or liver. Therefore, it is most useful for eliminating the side-effects of already approved medicines, such as in oncology. Basically, nano-capsules can reach cells and they enable the use of smaller doses. Our innovation in this area is focused on

Grupo Neolpharma is a Mexican group that comprises several pharmaceutical companies: Alpharma, Neolpharma and Psicofarma. It specializes in R&D, manufacturing, commercialization and distribution oncology and diabetes.

Q: What solutions is the group providing to the Mexican health industry?

A: We must first develop medicines and provide it to the greatest number of patients possible. In our case, this implies a national cost, which determines the price. We have done this with our product Transkrip, the patented version of which costs six times more. Our body is constantly defending itself against attacks and when certain cells get infected, they no longer work as well. Transkrip activates our cells to better absorb the medicine and in some cases it also reactivates the immune system. TransKrip is a drug based in epigenetic therapy that increases the progressfree period of patients with advanced cervical cancer. Currently it is used for cutaneous lymphoma of T-cells and myelodysplastic syndromes. We are completing a project on the application of this technology for lymphoma in D cells. In some cases it has 100 percent efficacy and there is a fast therapeutic benefit.

Q: Where is most of your R&D being carried out?

A: I am looking to mix research by stages, to do some in Mexico and some in the US. There is an innovation and development research center called Cediprof in Puerto Rico, a site that allows some of our research to be conducted in an FDA environment. This is a strategy we want to extend to other Mexican companies that are working on innovative projects, so they can develop the early research phases in Mexico and then conclude their research in Puerto Rico without a major investment. This will create fiscal benefits and empower research.

Q: What opportunities will IMSS opening to clinical research bring for Grupo Neolpharma?

A: That is extraordinary because it is where the most patients are. For example, the application of the D-cells treatment is valid only for a small number of sick patients with those characteristics. IMSS is where most of them are. In the INCan, the process of incorporating the number of required patients was long. However, with IMSS we can more quickly identify people with a certain condition and deliver the product.

PUSHING PATENTED MEDICINES INTO THE IMPULSE CHAIN

JUAN AGUIRRE

Commercial Director of Grupo Bruluart



Q: How is Grupo Bruluart working to make patented medicines more widely available?

A: One of our biggest projects has been pushing lines of patented medicines into the impulse chain. Besides the old big distributors, there are several pharmacies, clinics and other retailers where patented drugs are sold. It was thought the most economically challenged social group would not buy patented medicines because of the high price but some prefer to acquire medicines at their local pharmacy.

Q: What were the advantages of being ready six months in advance before the change in NOM - 059 in 2016?

A: It helped us get ahead and minimize the effort needed to comply with the standards. Since we were ready, the number of topics we had to cover once the norm was approved was small so we did not have to dedicate many resources to it to comply. We also founded the Instituto de Farmanegocio, through which we provide an integral advisory service, guiding our clients step-by-step to meet COFEPRIS, SAT and other regulatory requirements. Some of our customers are taxed according to the small contributor regime. As a result, the taxes of those companies are sometimes in disarray and they fail to meet regulations. We have convinced and advised several customers to fix their fiscal situation so they can access various benefits and minimize the risk of not meeting fiscal and health regulations.

G: To what extent do your products target specific niches? A: We started selling generic drugs that target the general population, such as painkillers, multivitamins and antibiotics. Now we are specializing in the hormone niche, especially in contraception and hormonal care, because there is less competition and only a few can develop injectable contraceptives and hormone drugs. There is a learning curve with hormonal medicine so we have been focusing on these areas for around two years. It is difficult to come up with a market percentage but we manage three of the top 10 products in the public sector.

Q: COFEPRIS is liberating several packages of innovative medicines. How is that affecting Grupo Bruluart?

A: We are working on these liberated molecules. COFEPRIS has developed a useful strategy based on risk assessment and this patent liberation makes the register of new and generic products more efficient. We can now get generic drugs to market much faster and even expect to release between six and eight products this year from the packages of 2016 and 2017 in hormonal treatments, some in painkillers and anti-inflammatories.

These areas were chosen because we have noticed that painkillers and anti-inflammatories have undergone a similar process to that of antibiotics in the past. People have become accustomed to consuming them without a prescription, developing a higher tolerance to painkillers, so we expect the new molecules to have a more efficient effect.

Q: What are your ambitions and plans for 2017?

A: We have already expanded production at our plant, partly due to COFEPRIS' regulations. We are complying with all these regulations and are ready to continue our growth in the manufacturing business through development of more products. We are looking for new international ventures for products we sell in large volumes, such as paracetamol or diclofenac, which in Mexico are largely sold as commodities and have a better margin elsewhere.

On the commercial side, Farmacias GI has a new image and an aggressive expansion plan that includes the launching of a new media campaign. In the distribution business, our goal is to train independent pharmacies. Many of these are important to rural communities and underdeveloped parts of the country. We are also expanding our business by visiting convenience stores and large national chain pharmacies to address a renewed interest in our products in sectors that traditionally were not attracted to generics but now cannot get enough of them.

Grupo Bruluart includes the importer and manufacturer IM Bruluart, Laboratory Bruluagasa, generics company Brudifarma and pharmacy chain Farmacias GI. Its goal is to make highquality medicine accessible to all



GENERICS FIGHT BRAND BIAS

AMÉRICO GARCÍA

Director General Latin America of Apotex

Q: What is Apotex's strategy for launching its products in Mexico?

A: Over the past 12 months we have been first to market for mometasone, a nasal spray for rhinitis and allergies; diosmin-hesperidin, for chronic venous insufficiency; leflunomide, on the side of rheumatoid arthritis and we are now launching tramadol-paracetamol, a painkiller for moderate to severe pain. We are reshaping our strategy to be more active and efficient in product launches. The company is targeting different opportunities in the generics segment and launching a broad portfolio in CNS products, which comprises antipsychotics and antidepressants, among others. We will launch over 25 products in three years through a full portfolio with a different strategy targeting physicians, which is unusual for Apotex. The company will also introduce some branded products rather than simply generics to complement our product lines. The use of generics in Latin America is different to North America and Europe. It is still generally a branded market. Bioequivalent products are not available in every Latin American country for example. Patients associate brands with quality so, despite the quality of bioequivalents, there is still a preference for brands. We are catering to the demands of the market.

Q: Why do generics generate this level of resistance?

A: Generics have come a long way. Initially regulation was not so strict, so in those days there were products that did not comply with international quality standards. This bias still exists but regulation is now stricter. COFEPRIS is overwhelmed with the work of auditing all manufacturers and ensuring the stricter requirements are properly covered. This is an issue and some will be left behind because they cannot keep up with rising standards. They would have to invest a lot of money to catch up.

Q: What problems do you see with the bidding process established by the government?

A: It changes constantly. At the moment it is talking about packages, which we are still trying to understand. Packaging is more complex because it is not possible to have every product. There are some requirements that are impossible for us to meet so we need to use distributors. I think the bidding process will make some distributors stronger than they already are and that concerns me. For example, a hospital far away in Hermosillo may request a product within 24 hours. For this, we need to work with a distribution company that has its own center because Mexico is five times the size of France and we cannot deliver any given product anywhere in the country within 24 hours. To become more efficient, healthcare providers are ditching their warehouses and we are becoming their warehouse. We also must have different logistics partners because some prefer to work in certain therapeutic areas or in specific regions. Ahead of a tender, they want a letter of endorsement that says we will supply them with a certain product if they win. We sign with the minimum volume and price and if they win the tender, we sell the product to them. Some tenders are national, international or mixed. It is not that they actually want to bring in someone from the outside but it happens that no local company can meet the requirements. We participate as a national company if the product is manufactured in Mexico and international if it is manufactured in Canada or India. Products made in India are more problematic because the tender process generally does not accept these, perhaps because the government is not confident about the quality.

Q: How is the authorized third-party system working?

A: It works well. It costs money because we have to pay for the service but we get faster approvals. It is beneficial to us and to patients, who get new products sooner, and puts lower-cost generics on the market faster. Some Big Pharma companies are trying to extend IP protection, looking for opportunities in the legal framework. As patients and consumers, we should not allow this. At Apotex Mexico we respect patents, of course, but they should not be extended for reasons that do not represent real invention.

Q: How much R&D is done in Mexico and how important is that to the development of your business?

A: Most of the R&D is performed in Canada but our Mexican research complements our efforts in R&D and is more focused on local needs. Canada focuses on the big markets like itself and the US, while in Mexico we look at Latin American opportunities to complement them. We have developed 55



products in our local facilities and many more in Canada. In Mexico, we invest 6 percent of sales revenue in R&D and 4-6 percent more in renewing equipment to improve our technology. Canada invests a much higher percentage.

Q: What types of drugs are researched in your Mexican facility?

A: I have been working on getting back to basics, reshaping the organization's main activities, and then working a little on the strategic view of where we are going. Over the past few years we have been focusing on doing things better rather than on specific therapeutic areas, except for the CNS line. What we are doing now is aligned with the opportunities we see to penetrate segments in which we do not yet have a presence.

Q: Has the peso depreciation affected your operations? How do you mitigate currency risk?

A: It has affected us, of course. We try to not transfer the full impact to our customers. The company is absorbing some of it by developing efficiencies. Some we are tackling now, improving efficiencies and productivity. We are also trying to develop the export segment because we export in a hard currency. When reviewing market figures, it is possible to see that Apotex is not raising prices as quickly as inflation or in line with the currency's depreciation. My view is that we will be depreciated, but with the fundamentals under control it will be strategy more than a consequence. We export a good number of our Mexican manufactured products to South America. We negotiate most of those sales in dollars, which mitigates the effect to a certain extent.

Q: What expansion plans do you have for the coming years?

A: We manage the LATAM region from Mexico. Now we have three affiliates in Panama, Nicaragua and Costa Rica and we already have partners in Guatemala, Dominican Republic, Chile, Argentina and we are about to close a deal for Colombia. The generics segment will remain one of the main sources of growth for Mexico. We will continue to expand to new therapeutic areas, such as prescription. We will start with CNS over the next three years. It will take us that time to gain the relevance we want to have in that area and then I will jump to another therapeutic area. Apotex has been a leader in Mexico since it entered the country. We are celebrating 20 years here and 41 years in Canada. We are one of the few vertically integrated companies, with two API manufacturing sites in Mexico. For 60 percent of our products manufactured in Canada, the APIs come from our Mexican sites. We are committed to this country like no other company.

Q: How does the legal environment protect generics companies from litigation in Mexico?

A: We still have to work on this. We need to get together and be more visible to the authorities to make sure we are being treated fairly. Being close to the US in general helps because we want to be recognized as a highly regulated country that can manufacture products that can be sold everywhere. As we deliver on that, it becomes easier to build trust.

Q: How has the wave of patent expirations benefited Apotex?

A: The products I mentioned for which we will be first to market have expiring patents and we are using the opportunity as soon as we can. This is happening across therapeutic areas. For the CNS line, it will be branded so we do not need to launch the product as soon as the patent expires. For generics however, it is vital to be first.

Apotex is the largest Canadian-owned pharmaceutical company, with over 10,000 people employed worldwide in its research, development, manufacturing and distribution facilities. The company produces around 300 generic pharmaceuticals

INSIGHT



MANUFACTURE LOCALLY TO CREATE AFFORDABLE PRICES

GURULINGA KONANUR

Director General of Hetero Mexico

Generics provide a cost-effective alternative to branded products, allowing for more accessible healthcare. This is important as the general population is more financially able to purchase the treatment it needs and the public sector health institutions are able to purchase a larger quantity of drugs. Despite initial reservations, the generics market in Mexico is growing, mostly due to government consolidated purchasing preferences for generics as it allows the treatment of more patients on a shrinking budget.

Hetero Group, an Indian generics company, is one of the main manufacturers of antiretroviral therapy drugs (ARVs) worldwide with a third of the world's market share. "For every three patients, one is taking a Hetero product either directly or indirectly as we supply APIs to other suppliers," says Gurulinga Konanur, Director General of Hetero Mexico. "We want to bring all these high-tech, high-specialty products to Mexico, manufactured locally at an affordable price," he says, adding that the company expects Mexico to be among its best growth performers in Latin America. "The generics market in Mexico is growing over 20 percent per year and even branded generics are growing when compared to innovative products."

The general population is also increasing its generic purchases as many must pay out of pocket in one of the most privatized healthcare systems in the world. The OECD reports that only 5.8 percent of GDP in 2015 in Mexico was spent on healthcare, almost half of which was out of pocket. Indeed, access to healthcare is one of the greatest challenges facing the Mexican healthcare system. INEGI figures show that only 62.2 million people had access to IMSS services as of July 2016 and despite government efforts, this figure represents only a 33.3 percent increase in the 10 years since 2006.

The prevalence and availability of generics is important for pandemics such as HIV/AIDS because drugs for these diseases can be expensive and are needed by many. HIV/AIDS treatment in Mexico is free for all, whether registered with a health institution or not. It is therefore important for drugs to be cost-effective. In 2015, the National Center for the Prevention and Control of HIV/ AIDS (CENSIDA) reported around 200,000 people living with HIV in Mexico and an estimated 100,000 new infections. UNAIDS estimates there were 4,000 AIDSlinked deaths in Mexico that year.

Although generics are growing at a faster rate and allow for better access, the population continues to demonstrate a brand bias, showing a preference for branded generics. "I think over 70 percent of the Mexican population would look for a good branded generic," says Konanur. He adds that although it took some time for branded generics to be accepted, doctors are now comfortable prescribing them. "Pharmacists also encourage generics. They receive many kinds of incentives to promote the generics of the pharmacies they belong to," Konanur says. This is most likely aided by the fact that many pharmacies stock their own-brand generics and are looking to boost sales, he says.

Another main issue with access to medicine is the growing counterfeit or black market. Many companies are taking precautions to ensure they are not inadvertently participating in this by ensuring both their medicine and packaging does not fall into the wrong hands, says Konanur. He explains that the generics sector is seemingly less affected because the products are cheaper and more widely available, adding that it is often the larger names that are subject to counterfeit, just as in other sectors. "I have not seen as many issues with counterfeits in generics as in innovative products. The sales margins are smaller in generics so they are not affected so much," says Konanur, adding that his company employs many innovative packaging techniques that make the boxes difficult to imitate. "We have one of the most innovative packaging departments in the world."

To further expand its Mexican presence, the company has acquired land near Toluca and expects to be manufacturing products from a custom-built factory there by the second quarter of 2018. "We are in the planning stages and by January 2017 we will be kick-starting construction," Konanur says, adding that foreign investment has aided the process.

THE ANSWER TO TOP HEALTH CONCERNS: TECHNOLOGY



JUAN PABLO SOLÍS

Vice President and General Manager of Becton Dickinson Mexico, Central America and the Caribbean

Q: How important is Mexico to Becton Dickinson's global position?

A: Mexico has long been a successful market for the company. The country is the second-largest market in Latin America after Brazil. Over the years we have gone from being a syringe company to taking up a leading position in clinical diagnosis, molecular chemistry and flow cytometry markets. Of Becton Dickinson's (BD) 45,000 global associates, 9,500 are Mexican, nearly 20 percent. They are distributed throughout our operations in Mexico City, San Luis Potosi, Sonora and Baja California. We export products made in Mexico to the US, Asia, Europe and the rest of Latin America. Our success in Mexico can be explained through our commercial and manufacturing history of over 60 years.

Q: How has Becton Dickinson permeated the Mexican market to ensure continued growth?

A: 2016 was an important year for BD. Globally, it was the first year we operated with the integration of Carefusion, acquired in 2015. Carefusion has a strong portfolio of innovative products and with this alliance, the company widened its footprint around the world. In Mexico, BD consolidated its market leadership, focusing on providing solutions for the country's main health issues. We are relevant in key fields such as women's health and cancer we produce the best technology for the early and accurate integrated diagnosis of cervical cancer. We continue to be an important player in healthcare worker safety, providing a wide range of products that make clinical and medical practices safer for Mexican professionals, and we are becoming more relevant in diabetes management, with a large percentage of patients using our specialized syringes and pen needles for their daily care.

Q: How can BD technology help to improve the effectiveness and productivity of the Mexican public healthcare system?

A: Many innovative medical device companies, including BD, offer a set of products that in the short-term may appear to be more expensive than traditional devices. However, the new features, such as safety for healthcare workers and for patients, bring benefits in the long-run for the healthcare system. If a patient can be treated with stateof-the-art medical devices, it is more likely he or she leaves the hospital sooner.

Q: What business models help keep high technology affordable for the public and private sectors?

A: We work on different axes, first generating local clinical evidence about the benefits of our innovative products to the healthcare system, then early adopters among public and private institutions embed the new technologies. Once a product is proven to work, the system tends to adopt it *en masse*. At Becton Dickinson, we have a wide range of products that are affordable depending on the need, which is why we play at different levels of the healthcare system, following our purpose to advance the world of health.

Q: What is Becton Dickinson doing to support the digitalization of the Mexican healthcare system?

A: We have several technologies that support healthcaresystem digitalization. Through our solutions for lab automation, for example, we can connect different instruments to link clinical results to a lab and a hospital database. Our value proposition in medication-management systems can help with drug/patient traceability that is so badly needed in our country to avoid medication errors.

Q: What type of technology have you developed for the protection of healthcare professionals?

A: We have developments designed to prevent accidental punctures. A traditional syringe has a barrel and a needle, so when nurses give an injection, they are vulnerable to punctures. With our system, once the injection is made, there is a mechanism activated by a spring that covers the needle. These security products have seen great acceptance in the private sector and we want to show the benefits of this line to public institutions. Our clinical evidence shows that using these products greatly benefits the entire healthcare system.

Becton Dickinson is a US-based international health technology company focused on IV devices for drug administration, cancer diagnosis, diabetes treatment and cellular research



CHANGE IN FOCUS FOR MEDICAL DEVICES GIANT

ALEJANDRO PAOLINI

General Manager of Siemens Healthineers Mesoamerica

Q: There is a trend toward deregulation of medical devices in Mexico. How does this impact your operations?

A: This trend is good for us as long as it is done intelligently and efficiently. Regulation is a difficult topic because our industry is highly regulated in all parts of the world and it has to be protecting the population. However, it must also be efficient and not be an obstacle for the population to have access to the latest technology. A balance must be struck between protection and access and I believe COFEPRIS is working on this in an intelligent way. What is important is that COFEPRIS has maintained an open dialogue with the industry and we need to talk with them through our associations such as AMID and CANIFARMA. Serious companies want a regulated industry but regulation that is efficient enough to avoid being an obstacle.

Q: What growth has Siemens Healthineers seen in 2016? What were the main drivers of this?

A: In 2016, Siemens Healthineers Mexico had a good year considering the context. We had double-digit growth, so we can say that it was a good period in terms of revenue, as we had many orders pending from 2014/2015. In terms of new orders, we continued to grow but this slowed down and we ended 2016 with high-single digit growth. We gained market share and we grew above the market, but it was difficult because of the peso devaluation against the US dollar and public budgets being cut due to a drop in oil prices. However, it was stable thanks to the private market as it continued to invest despite the fact that the public market contracted.

Q: How has rebranding as Siemens Healthineers boosted Siemens' image and operations? What benefits is it bringing to your operations and clients?

A: The new brand is just the final stage of a bigger process that began with the separation of the healthcare business into an independently managed business. The second step

Siemens Healthineers is the healthcare branch of the German electronics giant. It is mostly known for its medical devices, which cover a wide range of therapeutic areas, with a focus on diagnostics, imaging and IT was the implementation of the new strategy. Then, a new structure, new business principles and corporate values and the introduction of the new brand came. The main benefit is that we have gained speed to react to client and market needs. Siemens is huge and diversified. Total revenue for health is €15 billion compared to over €80 billion for Siemens as a whole. In addition, there are many synergies and similarities between the other parts of the business, although not for healthcare. We can now take strategic decisions faster. If we want to make an M&A decision, take a new strategy or create new products we no longer need to refer back to Siemens. The brand name is to give us a specific identity. Not everyone understands the meaning at first but Healthineers expresses our engineering and pioneering background applied to the healthcare industry.

Q: In 2016 you reached agreements with hospitals in Turkey. To what extent is Siemens interested in agreements with hospitals in Mexico?

A: We absolutely are. At the same time as continuing investment in new products and R&D, we want to expand our business into new services related to our products. That is the final goal: to be the enabler or facilitator of healthcare providers, enabling them to perform better with higher output and lower costs. We are not looking for any specific types of hospitals but it would have to be at least a midsized hospital as this is not the type of project that could be implemented with a small hospital.

Q: In February 2017 Siemens announced a US\$200 million investment for the next 10 years in Mexico. How much of this is going to healthcare?

A: A small part of it will go to health. There are factories and development centers related to the other businesses but it would be difficult to have local production for health. The typical example is magnetic resonance, as the annual Mexican market is probably for around 20-25 systems. This is not mass production, these are high technology products and manufacturing is concentrated in one or two places across the world. This is why healthcare will only receive a small part of the US\$200 million because most of it will go to plants.



ARTICULATE GROWTH FOR MEXICO

NELSON VALENZUELA

LATAM and Caribbean Director of Arthrex

Q: What is your view on selling through public tenders in Mexico?

A: Due to the market niche we work in, we are obligated to deal with huge distributors that offer integral services, which is complicated. They consolidate several brands and sell a complete service to the hospitals of IMSS and ISSSTE, although PEMEX, SEDENA and SEMAR have remained outside this model. Both IMSS and ISSSTE classify Arthrex's technology as minimally invasive (MI) and 90 percent of these MI procedures are abdominal, while 10 percent is for joints. This turns into a fight every year as the volume reduces. Being only 10 percent of the contract, distributors do not place the same emphasis on arthroscopy. The ideal scenario for us would be for integral services to end or include arthroscopy in orthopedic tenders. Ideally, we would provide services directly to government institutions but they never have the budget to buy everything.

Q: What is Arthrex's strategy to expand its reach in the private market and to stand out against its competitors?

A: We have learned we need to analyze more factors before making the decision to launch a new product, to focus on more profound marketing studies using a sniper technique. Globally, Arthrex has 12,000 products, of which 2,600 are available in Mexico, which is the right number of SKUs based on the Mexican market's need. This has enabled us to see growth rates of 17-18 percent in the country. Another key point is service: when we sell an anchor, we are also selling the accompanying equipment and a technician to help. For MX\$25,000 (US\$1,389) worth of sales, we have to move MX\$600,000 (US\$33,000) of equipment, products and personnel. We have to define our service standards and stick to them. We go with a full set of equipment, the instruments are in perfect condition, the technician will be well-trained and we will be there for anything needed. This reinforces our credibility with doctors.

Q: Which products are you bringing to Mexico?

A: We do not want to deprive Mexico of innovation, so we work on a diversified portfolio for A and B markets as physicians move between distinct hospitals and different reimbursement scenarios. In Mexico, the most common surgeries would be shoulder instability, rotator cuff tears, anterior cruciate ligaments rupture, meniscus reparation, syndesmosis, Achilles tendon repair and internal braces for ankle stability. These seven surgeries all have an A and B portfolio available in Mexico.

Q: Arthrex has an educational center in Florida. To what extent does the education you offer in Mexico help doctors improve their skills?

A: In addition to the Florida Center we have one in Mexico and one in Brazil because we have the obligation to correctly train doctors to use our products. The courses are open to everyone, even those who do not use our products. Some courses are available online through Arthrex's webpage, which puts over 4,000 videos online, and through our Surgeon's Virtual App, which enables doctors to first practice digitally before moving onto dry labs. In our labs we use imported cadaveric pieces from the US. Unfortunately, in Mexico the culture of organ donation is poor and if we have chance to use a Mexican cadaver, the law is clear, demanding use of the full body. Can you imagine putting a full body on a table just to practice on the knee?

Q: What is the most important product you will be launching in Mexico in 2017?

A: Apollo, a bipolar radiofrequency for arthroscopy. It will be brought to Mexico in July 2017. Arthrex has the fastest processing times of all medical device companies in Mexico and our products are approved within an average of 60 days. In our 2015-2016 financial year, we registered 102 products. The priorities will be to maintain operational excellence and for our sales team to begin identifying new opportunities and to relaunch technologies that did not have the initial impact we had hoped for. The second priority will be human capital management. The third point will be to continue our great work in compliance as a way of business.

Arthrex is a medical devices company and a leader in new product development and medical education in orthopedics. The US-based company is a pioneer in orthobiologics, arthroplasty and in the surgical treatment of arthritis



EASING ACCESS TO INFORMATION

XAVIER VALDEZ

Director General of QuintilesIMS

Q: Last year, IMS Health merged with Quintiles to become QuintilesIMS. What are the resulting benefits and what new services have been integrated into your portfolio?

A: We inherited clinical research services from Quintiles and today we can offer its clinical studies portfolio for phases II and III and our own for phase IV on observational studies. Thanks to the merger, we have a stronger capacity to offer follow-up services when launching a product. Of course, we are still in the process of completing the merger.

Q: What role does Mexico play in QuintilesIMS' global strategy?

A: The country has the potential to become a pioneer for clinical research and for launching new products. The world invests around US\$162 billion, Latin America captures US\$6-8 billion in clinical research and Mexico could attract a bigger slice of that pie. The goal is to make this innovation available to the medical community by integrating it into institutional purchasing.

Q: Which of your areas of operation attract the most focus: information, technology or consulting?

A: Before QuintilesIMS, IMS Health participated in the information segment and later it developed additional businesses, with a consultancy department, technology and design. With all the recent possibilities in information management, the next step is to take advantage of the technology tools that allow us to do analysis and answer more questions about the effectiveness of treatments, disease management and the efficiency of sales force resources.

Q: How does QuintilesIMS approach its solutions to offer added value for its clients?

A: Almost all our projects are tailor-made. We analyze the efficacy and efficiency of the products each laboratory

QuintilesIMS is an American multinational company offering intelligence solutions for clinical research and commercialization services to help companies reach the market in a faster and more cost-effective way manufactures and the benefit and cost to the customer. We also analyze the product portfolio strategy to understand where the laboratory should filter its resources to achieve a better market result. In addition, we customize research to understand why doctors prescribe a specific drug.

Q: What new product launches is the company planning for 2017?

A: We are launching the Prescription Based Service (PBS), a database of over 45 million prescriptions built by pharmacy chains, our commercial partners. With this system, our laboratory clients can see how they are positioned with doctors, based on the prescriptions those doctors write. They can also see what a doctor prescribes and what each doctor uses for certain diseases. We are also interested in developing a platform to provide doctors with information and we want to do observational studies to see what happens with patients after drugs go to market.

IMS Health also bought a company that provides certifications for clinical and patient services in hospitals. The company uses a series of indicators to evaluate the different services a hospital offers and the institution receives feedback showing where it must improve. We are planning to extend the operations of this new company to Mexico and offer the certification. It will help patients rate hospitals, allow insurance companies to be aware of who they are working with and give hospitals information on areas for improvement. We are also working with COFEPRIS to develop a platform where doctors can receive embargoed news releases.

Q: Digital health trends include digital interventions, data integration and analytics and behavioral health. What are the key innovations in Mexico?

A: In Mexico, we are talking a lot about Big Data. However, we are still in the early stages because to make Big Data work we need solid information, visualization and capture systems. In Mexico, some hospitals should have a system to manage information on chronic diseases that can feed indicators that track the evolution of these conditions. It is important to establish the foundation that will keep the system fed. If we do not have that ready, we could fall behind other countries.



DIVERSIFICATION KEY TO GROWTH

CARLOS PÉREZ Director General of NYCE

Q: What aggregated value does NYCE offer that gives it a competitive advantage?

A: Third party organizations create standards for the industry. NYCE has an 18-year-old quality system that relies on the constant improvement of our activities. In our healthcare division, we have three elements to achieve this. First, our management system must control and define metrics to improve our efficiency. Second, we have an internal program called Unifying Hands and Efforts through which collaborators suggest initiatives. Our third element is the satisfaction surveys we send to our clients, where we measure market perception and receive feedback. These three improvement tools have helped us achieve an average of 97 percent customer satisfaction.

All 330 of our staff members have been trained in client service. In fact, we trained COFEPRIS staff on the same subject because it is one of our strengths. Our last COFEPRIS audit was excellent, which motivated us to participate in the National Quality Price. Those are elements that give us a competitive advantage against other companies.

Q: How can you improve processing efficiency for your clients?

A: In January, we launched an online system to assist clients. We have already implemented electronic tools for many of the other industries we work with. In oil and gas, electronics and communications we have a secure online depository to protect information. If an industry accepts our security measures, a confidentiality agreement and responsibility for information management, companies will not have to be present physically for every procedure they need. They will save time and money with us. We are an organism that certifies information security through ISO 2700. We are certifiers of personal data security, giving us another competitive advantage.

Q: What type of healthcare companies are you focused on certifying?

A: When we first started our activities in healthcare, we noticed a large need for medical devices. We focused on that but then we realized that the existing number of authorized third parties fully covered the devices sector, while medicines were ignored. In 2015, we did not reach our pharma goals. Therefore, in 2016 we changed our strategy and focused on medicine rather than medical devices. It was a challenging decision because drugs require much more responsibility and capacity than the other business line. We are working with Pfizer and more organizations are considering our services, mainly because we provide additional benefits. This has given us the opportunity to register several specialized operating cells during 2016.

Q: What does NYCE need from COFEPRIS to improve its operations?

A: The creation of the authorized third party system was a great decision. The government's acceptance that its internal structure could not deal with the volume of demand was a good move. We have 22 years of experience as a standardization organism, 21 as certification institution and 20 as a verification unit. However, we recognize some third parties are facing operational constraints. The new NOM-057 regulates the pharmaceutical industry but authorized third parties are not allowed to provide certificates under this standard. NYCE is allowed to verify food content labels for the alimentary industry but is not authorized to verify nutritional information, despite the fact that we operate in the health industry. If we want integral solutions for the market, we should be able to offer both services.

Q: What are NYCE's plans for the near future?

A: We want to grow our market access by regionalizing our services. We can help organizations export their products to other countries of the Pacific Alliance. Hypothetically speaking, if COFEPRIS closes an agreement with the regulatory authorities of the Pacific Alliance countries, authorized third parties would be able to provide services to the whole region. It is an idea that may help many players in the system.

Normalización y Certificación Electrónica (NYCE) is an authorized third party that certifies electronics, medical devices, medicines, information security and food labels. It is looking to further expand its operations



MARKET FACTORS DRIVING GROWTH, WEB SALES IN FOCUS

VÍCTOR SOTO Director General of Levic

Q: What main changes did Levic's operations undergo in 2016?

A: We amplified our portfolio, opened a new distribution center in Vallejo and worked to improve our service. We are a distributor of mostly generic medicines and we have greatly improved our just-in-time model. The company already has a strong portfolio in generics, herbal medicine and wound care, so we have mostly expanded in prescription drugs from transnational companies, which have a slightly higher cost. Our work with transnational labs has grown by 60 percent but in general Levic saw growth of 14.5 percent in 2016.

Q: What have been Levic's main drivers of growth?

A: Market factors have driven our growth, while prices and accessibility have been fundamental over the past 10 years. Information has also pushed growth because people are increasingly aware and have access to more information. People now know that patented and generic medicines are the same. The difference is only in the cost to patients. As Mexico is an emerging economy, people need medicines and need to be able to obtain it. This theme of accessibility has boosted growth for us.

Q: To what extent does Levic work with the public sector?

A: Only around 2 percent of our sales go to the government, while the other 98 percent goes to the private sector. Previously, a cure for a general illness cost MX\$500-1,000 (US\$28 -56) out of pocket to pay for a doctor and medicine. Today, patients can receive medical care and medicine at many pharmacies for MX\$150-250 (US\$8-14). Because of this not everyone needs to use government services.

Although we have no plans to change our sales ratio, we will need to work more in other areas, including the government, to maintain growth rates.

Levic is a Mexican distributor based in the State of Mexico that is specialized in the pharmaceutical sector. It began operations in 2000 as a generics distributor and has expanded operations throughout Mexico

Q: How is technology impacting the logistics business and your operations?

A: We are investing in R&D to allow our customers to buy from us online. We have a web portal that clients can log into and browse our catalogue of products and costs, and any order placed will arrive within seven days. We have been working on this since the summer of 2016 and it is continually growing. In the first month, sales were laughable, but by March 2017 online sales represented 9 percent of our total. We are promoting this directly through our sales force and through our logistics. We have no fixed target for where we want to be by the end of the year. It depends on what the market demands because our objective is to cater to market needs.

Q: How will you achieve your 2017 goals?

A: In 2017, we will begin operations in Monterrey. We are also working with restocking technology, that is to say robots that stock quicker than humans and with 99.9 percent exactitude. We are only missing a pincer in our stocking technology. Our goal is to implement this in four of our eight centers, three in Mexico City and one in Michoacan. Levic is working on a project in Central America and in 2017 we will enter the Belizean market, where we have a project with the government to send Mexican medicines there.

Q: How do you prepare for uncertainties such as strikes and protests?

A: Protests do not affect us much. What does impact us greatly is the *Hoy No Circula* (No Drive Day). In 2016, 40 percent of our vehicles could not circulate on any given day. With one No Drive Day per week, 20 percent of our vehicles are idle but with the double measure, two of every five are out of action. Distributing medicine becomes much more difficult. There are also security issues and areas we cannot enter because drivers are asked to pay bribes. We do not enter areas where the driver will be at risk, or when the risk is larger than the reward. If we were to push this, then we would be putting the health of the driver and the good condition of the medicine at risk.

LAB ACQUISITIONS BOLSTER BRAND VALUE



CARLOS OVIEDO Director General of GDA

Q: Lab acquisitions have helped spur GDA's growth. What is the strategy to integrate these labs?

A: Over the past two years GDA has acquired Olab Diagnósticos Médicos, Laboratorios Azteca and Laboratorio Clínico Jenner, which were the third, fourth and fifth most important players in Mexico City and its surrounding urban area and have made GDA the secondlargest player in the industry. GDA is now integrating the operations of these companies, retaining the best qualities and practices of each.

We are a multibrand group that will leverage operational and administrative synergies to enhance the value of each of our brands. Olab is recognized by many doctors and public and private-sector institutions for its expertise in imaging tests such as MRIs, tomographies, mammographies, x-rays and ultrasounds. Azteca is well-known for its leadership in clinical analysis, especially in forensic science and toxicology analysis, while Jenner and Swisslab are focused on disease prevention through clinical analysis. Although our brands have specializations, each has medical-imaging equipment.

We will concentrate our laboratory tests and analysis in a central location and our imaging diagnosis in a blue room, a model that will improve the quality and reduce time during the diagnosis process. The new 5,000m2 central laboratory will be robotized and will provide service to our brands, clients and other potential clients, both nationally and internationally.

We will continue to look for small to medium-size companies that complement the group's portfolio and we will also resume inorganic growth during the second half of 2017 through the expansion of our brands in Mexico City.

Q: How are these alliances impacting your operations?

A: In 2017, GDA collaborated with Grupo Diagnóstico PROA and Laboratorio Médico Polanco to establish the Mexican Council of Medical Diagnosis Companies (COMED), which aims to unite all the diagnostic labs in Mexico to help lawmakers improve current regulations. We also want to put regulation in place to ensure healthy competition while also organizing congresses and symposiums to spread knowledge and best practices in the industry. These efforts will translate into better diagnostic services in the country.

Q: How is GDA responding to Mexico's need for quick and precise diagnostics?

A: The group is joining forces with international suppliers to implement the highest available technology that will improve diagnoses. Our blue room has the technology to conduct live sessions between the treating doctor and our radiologists. The platform also allows us to share images with experts around the globe to improve the diagnosis in difficult cases.

Q: What is your strategy to put Big Data to use?

A: In this industry, Big Data applications should translate into timely disease prevention. In this area, we would like to cooperate with local governments and companies by sharing all the information we gather to increase prevention. The Ministry of Health is the appropriate entity to use this information for the benefit of Mexican citizens. We believe COMED will accelerate the creation of such synergies and regulations to help the Mexican population without threatening the privacy of our clients.

Q: What are your growth expectations for the following five years?

A: The president of Empresas Aries drafted an aggressive growth plan comprising organic and inorganic growth. This is why we are building strong foundations such as our new central lab, which will be 10 times larger than the current lab and capable of meeting our growth needs. Our goal is to increase our market penetration in Mexico and expand our coverage in Latin America. To achieve this, we will open several branches across our brands, mostly in the same markets in which we are already present. We also have a few companies in sight that will increase our national and regional coverage.

GDA was founded in 2007 in Mexico as a private equity fund focused on real estate and later expanded to other sectors. The clinical diagnostics unit GDA has become a leading industry player through various acquisitions

INSIGHT



PROGRESS STILL TO BE MADE IN DATA PACKAGE EXCLUSIVITY

ALEJANDRO LUNA

Partner and Life Sciences Co-Chair at Olivares

Intellectual property is preciously guarded in all sectors and countries due to its high intangible value and as a result, patent litigation is prevalent. According to PwC, four of the 10 largest initial adjudicated damages awards globally between 1996 and 2015 were in the health sector. NAFTA partners the US and Canada have beefed up their regulations and law firm Olivares says Mexico also needs to step up when it comes to data package exclusivity.

Olivares, a Mexico-based leader in intellectual property law, presented evidence to the regulating authorities for data package exclusivity to be changed, namely to mirror the rulings in other NAFTA countries. Whereas in the US and in Canada certain pharmaceutical products are protected for five years and new formulations and new indications are protected for three years, biologics and orphan drugs are granted 12 years of protection. "In Mexico, there is only an incipient and weak protection for five years, granted through an internal COFEPRIS paper that would have difficulty standing up in a court of law. Data package exclusivity terms remain at five years for biologics and orphan drugs. This is not satisfactory," says Alejandro Luna, Partner and Life Sciences Co-Chair at Olivares.

The firm has presented evidence to the regulating authorities showing that these drugs require over 12 years of R&D and therefore should be granted longer exclusivity periods.

"Most patent litigations occur in pharma because of the rise of generics. This began around 20 years ago and there is little case law to rely on because most cases were either settled or are still ongoing," explains Luna, who is negotiating on behalf of AMIIF in international free trade agreements. He is lobbying for a change in Mexican law in data package exclusivity and in patentability. He was previously negotiating for the TPP, and should NAFTA renegotiations go ahead, would look to represent the pharmaceutical industry.

In 2003, linkage regulations came into effect in Mexico to avoid these disputes. "The Mexican Institute of Industrial Property (IMPI) publishes patent registrations in its journal, which COFEPRIS checks before registering a new patent to ensure one does not already exist. In addition, the registrant must swear under oath that to their knowledge there is no other existing patent. Before this regulation came into effect, there were 20 compound molecules under litigation. Now, there are none," says Luna, adding that new formulations are the most commonly disputed. "The easiest way to fight an unlawful marketing authorization is to have it nullified, rather than filing an infringement lawsuit before IMPI, which can take years to reach a decision. By having a patent published in the linkage regulation it should prevent or nullify marketing authorizations in violation of patents."

Counterfeiting is often seen as a major problem in pharma. According to the US-based Pharmaceutical Security Institute, in 2015, there were 3,002 incidences globally of counterfeit medicine involving 1,095 pharmaceutical products. In Mexico, El Universal reports that between Jan. 1, 2007 and Dec. 31, 2015 the Attorney General's Office seized 945,152 fake medicines, just under 942,000 of which were confiscated in Mexico City. The Attorney General has been granted stronger powers in Mexico to pursue action against counterfeits without the prior authorization of the title holder, yet Luna believes that the most efficient course of action to reign in counterfeit medicine in Mexico would be to confiscate them at the borders. "Under current law, products cannot be seized because they are considered in transit between countries. If this is changed, it would be much more difficult for counterfeit products to make their way into the Mexican market." he adds.

To protect against counterfeiting, filing a patent is a necessary step. However, many are unaware of intellectual property procedures in life sciences, including in the highly patented pharma sector. Luna says this happens most often with researchers and universities. "Because they are often required to publish papers, they do so without knowing the intellectual property ramifications. Once a paper is published, the knowledge it contains can no longer be protected by IP law, which many are unaware of."

INNOVATIVE INSURANCE BRIDGES CARE GAP



PAULINO DECANINI

Executive Vice President of SiSNova

Q: SiSNova is a young company. What strategy has it employed to compete against established companies and new models?

A: Our differentiator is that we prioritize medical criteria over financial or economic criteria. Our offer is based on early prevention and the promotion of a change in healthcare culture. This has a significant impact on costs because if we change our habits, we can prevent chronic diseases and their related complications and if we detect diseases on time we can treat them before they become too complex and expensive. Therefore, our focus is on integral medical care, from prevention to treatment.

Changing healthcare culture is a long process, so first we want to provide access to immediate medical care without a direct cost for the user. We establish specific parameters to be able to provide follow-up and organize our insured population by demographic and epidemiological characteristics. We promote this by giving users benefits as they accomplish their goals, so they can have access to better services without higher prices.

Q: It says on your website that a new era in medical insurance began on May 2, 2015. How so?

A: This is because our greatest goal is to give the Mexican population more access to a better healthcare service with international standards and quality. Major expenses coverage was designed to avoid an economic rupture when there is a health problem within the family but the deductible and co-payment must be covered first by the patient. Insurance companies never cover prevention, primary care or early diagnosis. Everything is designed for treatment. Traditional insurance companies have tried to administrate healthcare with the goal of containing costs, but their policies are designed for major health expenses. This makes the system inefficient and this is one of the major factors why private insurance is so expensive in Mexico, and one of the main reasons why out-of-pocket expenditure is so high and increasing despite extensive healthcare infrastructure. Also, since public services sometimes receive a subsidy, the public believes it has the right to healthcare, but this comes at a cost.

Q: What is SiSNova's growth strategy?

A: We have agreements with more than 300 hospitals and 5,000 affiliated doctors across Mexico. In mid-2015, we did not have any clients but by the end of 2015 we had over 7,000. In 2016, we insured over 40,000 people and in the first quarter of 2017 we were near 50,000. The main internal drivers of this growth are our focus on medical care and our response to the insured patient. Once a user becomes a patient, we answer as a provider of medical aid not as an insurance company, recovering the essence of why someone approaches an insurance company, especially when they require specific medical care. We have a 99 percent policy renewal rate.

There are also external factors that boost this growth, the most important of which is the big gap that is not covered by the public or private health sectors. There are 121 million people in Mexico, around six million of whom have private insurance. But more than 30 million Mexicans belong to the C segment, where some have coverage but want to access a system with better services. Therefore, there still is a great opportunity to open access to the Mexican population. The public sector has limited capacity to offer punctual and complete service and the private sector is becoming increasingly expensive, leaving behind the larger part of the Mexican population. We grow by looking for new users and through references from our team and our clients.

Q: What are the company's objectives for 2017 and the coming five years?

A: We would like to keep growing at the rates we have seen so far. However, we are conscious that uncontrolled growth can affect the level of service in solving medical problems. The challenge is huge because the need is infinite. Our business is not to sell policies, it is to offer medical care with quality and security through an insurance policy.

SiSNova is a Mexican company attempting to change the insurance landscape, offering preventive services through policies aimed at those not covered by the public or private sectors



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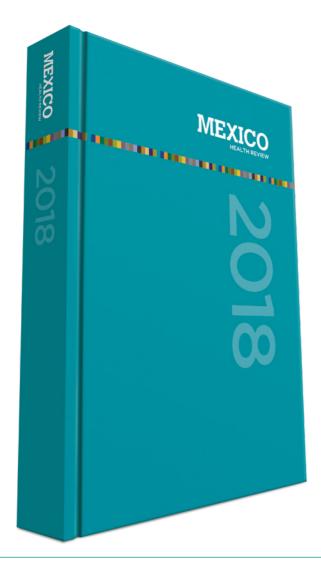
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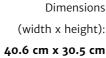


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