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Novartis strives for "creating solutions for patients that go beyond the pill". The country head and next president of CANIFARMA discusses how the company is using new programs and technology to get innovation to patients, how the recent work of COFEPRIS is helping get drugs to patients faster and why Novartis has doubled its investment in clinical research in Mexico.

You have been appointed as country head of Mexico in 2012. What have been your key priorities for the company since then?

Novartis' global mission is to save and change patients' lives and to do so the company is increasingly becoming a patient-centric organization. We strongly believe that as long as we bring product innovation and our models are tailored to better serve the patient, the economic results will come as a consequence. My tenure so far has had four key priorities, which are aligned with the company's global strategy. First, make innovation available to patients. Science got to a stage in the pharmaceutical industry, where we are not talking anymore about incremental innovation, but about disruptive improvement. And at Novartis we have a vigorous pipeline of new products that are real game changers. Next, creating solutions for patients that go beyond the pill. In Mexico Novartis is the only drug manufacturer that has launched an e-card-based loyalty program, which provides useful information both to the physician and the patient about patient's treatment

adherence as well as additional benefits, such as tips on how to better manage the disease. Also, we have been partnering with healthcare authorities to deliver better outcomes in the therapeutic areas we focus on. We have taken a leadership role in researching and discussing outcomes for given diseases and propose better treatments. Last but not least, we are committed to tailor the company's strategy to the needs of Mexico, both in terms of healthcare system and epidemiological profile.

What have been the most important milestones of Novartis in Mexico over the past couple of years?

Since innovation is the essence of our business, new product launches always represent an important milestone. Last week we launched the first-to-market combination in the area of COPD (chronic obstructive pulmonary disease). A further milestone I feel especially proud of is the approval of national reimbursement for seven of our drugs at the General Health Council. We have a terrific 80 percent approval rate with the Council, which is three times the industry. Now, bringing them into the different institutions of the social security system is the next step.

The third milestone has been the recognition of Novartis as the best pharmaceutical company to work for by the Great Place to Work® Institute in 2013. We also won some additional CSR prizes with regard to diversity. Novartis is increasingly being recognized in the country not only as a company which delivers pharmaceutical innovation and partners with the government, but also as a social responsible company fostering diversity and work-life balance. We currently have more women than men here in the Mexico office, which is very good news. We always strive for diversity and now even have some departments where we have to get more males, as we only have women!

How are you working with Mexican health regulators to make sure medicines are listed in national formularies, thus innovation gets to patients?

We need to bring innovation in an economically responsible way. Most of our new pharmaceutical treatments have been presented using pharmacoeconomic models that show we can deliver better outcomes to patients and do it in a very price sensitive way. To make sure patients can benefit from new medicines as quickly as possible, we conduct clinical trials to generate the necessary data.

We have increased very significantly our footprint in terms of clinical studies in the country and we are increasingly not only delivering data, but also investing in local R&D to make innovative treatments available to a good base of patients by partnering with medical academies and institutions. As a result, we have doubled our investment in clinical research in the country. In 2013

the company invested more than USD 2 million in R&D that support approximately 40 clinical trials which involve almost 28,000 Mexican patients.

What competitive advantages does Mexico offer to conduct clinical research over other countries in the region?

First of all, cost competitiveness. The cost of running clinical trials in Mexico is economically efficient at a global scale. But beyond that, the regulatory framework created by COFEPRIS (the Federal Commission for the Protection against Sanitary Risk) has created attractive economic incentives to invest in clinical trials in Mexico. On the one hand, an accelerated approval path for products developed here. On the other, the recognition of COFEPRIS as a world-class agency makes the approval in other countries much faster. As a result, Mexico is increasingly becoming a regional hub for validating new molecules and bringing them in a fast and efficient way to the region. While a couple of years ago Mexico was lagging behind, thanks to the amazing job of Mikel Arriola, now the country's regulatory framework is at the forefront in the whole region. His role has been strategic: on the one hand to make processes efficient, on the other because they made a conscious decision to be strategic.

One of the strategic objectives of CANIFARMA (the National Chamber of the Pharmaceutical Industry) is to position Mexico as a hub for clinical research by 2020. What do you think about this goal?

I am very optimistic about this objective. In my new role as vice president of CANIFARMA, I was actually asked to lead the initiative to make this happen. Recently COFEPRIS and IMSS (the Mexican Social Security Institute) signed an agreement that opens up the institution to participate in clinical trials. As per today IMSS participates only in 8 percent of protocols, a very small number given the Institute is the largest of its type in Latin America.

This agreement is a milestone and I think it will really improve pharmaceutical R&D capabilities in the country. I hope COFEPRIS can get more recognition from other countries in the region, because if this strategy is fully implemented, Mexico could really become a hub for the approval and registration for drugs in Latin America — and that would be a game changer for the market.

We know Novartis has done efforts in the past years to diversify its offer and adapt to the needs of each market. Which therapeutic areas are growing most in Mexico and why?

In Mexico we have decided to focus on six areas. Oncology has been a key area in Mexico for the company for a while and we see a lot of traction moving forward, especially through cell therapy. Second, cardiovascular and metabolism. Recently a new molecule developed by Novartis has been proven to decrease heart failure by 20 percent versus standard care – an unprecedented result. We also have a very good footprint in the country in the area of hypertension and diabetes. Respiratory is also witnessing a series of disruptive innovations. CNS is also growing, thanks to innovative molecules in the areas of multiple sclerosis and Alzeihmer's. The fifth area is ophthalmology: we recently partnered with the local ophthalmological society for the World Sight Day, which took place on October 9, 2014 in Mexico City, and presented impressive numbers about how many cases of blindness are preventable. Last but not least, immunology and dermatology in which we rely on a globally a leading portfolio in the area of transplants and which also fits very well the epidemiological needs of the country. Renal disease is already the third largest and fast growing disease in Mexico, also because renal diseases are a consequence of the pandemics the country is experiencing in the area of diabetes and hypertension. Lots of patients are diagnosed late and have to go to dialysis, a treatment which provides very low improvement in terms of quality of life and is economically inefficient. Dermatology is also going to be a very active segment, as we are going to be launching some game-changing molecules in the area of chronic spontaneous urticaria and psoriatic arthritis. The Novartis' portfolio perfectly matches the current epidemiological needs of the Mexican population.

The annual reports states that "A consistent focus on three priorities – innovation, growth and productivity – across our portfolio guides every aspect of our long-term strategy". How will this reflect in the company's strategy in Mexico over the coming five years?

Innovation is mainly about the company's new product launches that is reflected in the very rich pipeline. But it goes beyond the product launches, because it also refers to how to bring innovation beyond the pill, for example using technology and new healthcare systems. The recently launched loyalty program is the only one in the country and is transforming into a platform with an app, which will allow patients to go to the pharmacy and get discounts and benefits as well as information about the purchasing pattern. We are also analyzing which country is delivering the best patient outcome for a given disease to analyze gaps and use best practices from other markets.

In terms of growth the priority is grow the number of lives we improve and save, so drug access is high on the agenda. Thus, we are partnering with the Ministry of Health to make sure innovation

gets to patients in an economically efficient way for the government. As with regard to productivity, we plan to make Mexico a hub for services across Latin America. Over the past years a series of back-office areas have been consolidated across divisions and countries and the HR hub has been located in Mexico. So far the experience has been outstanding, not only economically but also from a talent perspective, and only one year after its implementation, the area received some global awards for the quality of the services provided. This is generating good momentum to create additional hubs in the country, such as IT.

What is the major challenge Mexico is facing from a healthcare perspective?

The epidemiology of Mexico is becoming one of a developed country and it is the right time for government authorities and the industry to partner and rethink how the country will react to this challenges. The openness from both sides is there but it’s a serious task and we need to recognize that investment in healthcare in Mexico is well below benchmark, it’s 6.2 percent versus an average of 9.3 percent, and out of that almost half is out-of-pocket. We need to think at healthcare from a holistic perspective: if additional investment happens and it’s directed in a good way, it could have a good economic multiplier. Health should not be a cost, it should be a way to deliver economic growth to the country – and companies such as Novartis are ready to flank this.

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