

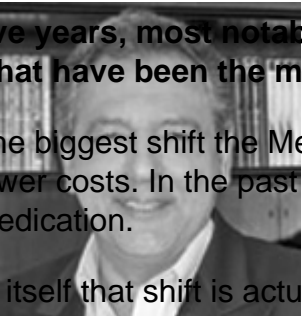
Interview with Ricardo Alvarez Tostado, CEO, AstraZeneca Mexico

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What are the most significant changes in the Mexican pharmaceutical industry in the last four to five years, most notably the new drug registration process being put in place. In your view, what have been the most significant changes, and how have they affected the market?



The biggest shift the Mexican market has experienced has been the fundamental move towards lower costs. In the past 4-5 years the explosion of generic has meant that consumers pay less for medication.

In itself that shift is actually good news for the industry, although in the short term it annihilates revenues by shortening the post patent-protected period and royalties of the products. Under normal circumstances that is not a bad thing. Other parts of the world, such as the US and Europe, have lived through this for many, many years.

For Mexico, it comes at a time that coincides with an industry-wide drought in innovation. So you get a little bit of "the perfect storm" in Mexico, where you have no innovation but an explosion of generics. Multinational R&D-based pharma obviously take a bigger hit than most.

On the other hand, if you look at the positive aspects I believe the current administration has taken the right tack by providing society with lower cost medicine, in principal of comparable quality to the original, through the regulatory changes that require generics to be bioequivalent. This is very positive because it should ultimately result in a healthier society with increased access to medication and increased productivity.

With regard to the regulatory environment, I believe that the administration undertook a humongous task, but underestimated the magnitude of the workload caused by the renewal process.

It is hard to argue against these initiatives because they are designed for the protection of the consumer with regard to pharmaceuticals; but it was done very slowly and became very cumbersome. I guess what was not envisaged at the time was the extraordinary workload in the pre-registration process, which also delayed the approval of genuine innovative products. In today's world, if we are going to make an impact we must have significant cost-benefit advantages, whether it be through improved efficacy or improved safety. Some of these innovations have suffered due to the extraordinary workload of pre-registration.

With hindsight, one cannot, criticize what has happened in terms of the intention of the state to provide greater access to quality medicines, particularly in the private market. However, the way in

which the regulatory framework was structured for this to happen has put big pharma at a disadvantage because of the delays.

Though we have seen improvement in recent weeks, we are still lagging significantly behind the 90-day approval time slot, where, if you did not get a response in that time, you would get official clearance to move. In today's world we are looking at anywhere from 18 to 24 months for approval and that is not just for new formulations, but also for formulation improvements. For anything that has to do with COFEPRIS, it is generally a very sluggish process. Although there is a clear intention to improve processes, there is still a long way to go.

Given the much wider access to lower priced generics, and the backlog in new registrations causing delays for innovative drugs, what have you done in AstraZeneca in order to get over these hurdles and harness new strategies?

AstraZeneca has a product portfolio that is very peculiar in comparison to other product portfolios. We tend to specialize in the more sophisticated medicines – cardiovascular, oncology, respiratory, and chronic diseases for example. As such, consumers have yet to learn, or feel, the level of trust required for this serious move into generics. Therefore, we have to concentrate on making sure those elements are well communicated to the market. If you do a historical comparison in terms of how industry moved its price-correction from 1997 to today, AstraZeneca has been a very responsible company in the sense that we preserved or maintained these common therapies within the prevailing access band.

For those products the advantage of generics at a lower price is marginal, so we have been able to sustain the bulk of our business in our chronic disease areas.

You mentioned the government and the move towards universal healthcare. Others we have spoken to in Mexican big pharma said that they have needed to be more innovative in the services they provide to the Government. Is this the case for AstraZeneca, and have you seen any big opportunities within the institutional market?

Most definitely. AstraZeneca was one of the early movers, along with Roche, in terms of strengthening our ability to service the needs of the state-driven Medicare provision. In that regard, I think AstraZeneca has positioned itself very competitively through the organization it put in place almost two years ago, anticipating that this is where much of our business growth would come from – mainly because of the overall improvement in healthcare in Mexico. You see that the population growth is just under two percent. However, if you look at the senior population, as little as 20 years ago we still had a life expectancy that was below standard for many markets. In today's world, that segment of society is growing at a six percent rate (three times the population growth) and obviously, the elderly will seek the reassurance of pre-paid medicine or sponsored medicine such as the centralized tenders.

I think for AstraZeneca that is where we are going to continue to provide improved services and where we want to go that extra mile for the government, by providing substantiated and irrevocable proof of the cost-benefit that our products provide to the institutional market.

At the same time, one has to realize that public healthcare systems have, as they do everywhere else in the world, enormous cost constraints because of the load that they carry.

Mexico provides a very uniquely generous market structure where you have the institutional sector, the private out-of-pocket segment of the market, and then you have the new up-and-coming popular insurance systems that will cater to those who have very little access to Medicare, if they have access at all.

So in that regard, I think the industry has to realign itself to make sure that it is able to provide adequate services to the institutional sector; provide broadened access to the out-of-pocket consumer, and obviously realign to be competitive in the Seguro Popular concept.

The important point is that while everyone sees the negative impact of the generics explosion, the benefit is that by alleviating the economic load for patients of high-priced medicines through generics, this in itself opens up economic space for future innovation. This is very important.

Unfortunately, the coincidence of the patent cliff with the generics explosion is a big headache in the short term, but if we look to the future I think Mexico, as it continues to move up the economic ladder- as Goldman Sachs has pointed out very recently where it projects Mexico to be probably the seventh largest economy in the world by 2020 - we need to find the power to be there. As the economic situation improves and as expendable income gets larger, so will the quality of medicine. I believe that there is still a lot of room for multinationals to preserve their presence in Mexico and to allow this readjustment of market pricing so it can cater for innovation.

One must not forget that generic manufacturers would not exist if we did not have innovative pharma. I believe that innovative pharma continues to look for new therapies in unmet medical needs. It will continue to provide healthcare solutions that improve both quality of life as well as life expectancy, and I think this is something that neither the state nor the consumer, should lose sight of. There is not a single state in the world that can actually fund the level of investment in research and development that big pharma conducts to find innovative medicines.

If you look back, I believe the bulk of common diseases areas have been well catered for, thanks to this innovation. However, we still have tremendous needs in the central nervous system area with senile dementia and with Alzheimer's among others, and in some of the more complex types of cancer.

So to summarize, there is still enormous room for innovation and thankfully there are some very dedicated scientists around the world who head up big pharma and look for these new drugs to provide better lifestyles.

You said in the future there will be broader access to out-of-pocket medicines; this presumably means lowering the prices?

Not necessarily. It could also mean adding value to our therapies through other means. One part may be alleviating the economic load of some of our products by way of providing in-compliance patients, or patients that are not adhering to treatment, economic relief. Another part may be to provide additional services such as dietary guidelines, and a number of added value items where the patient recognizes that somebody besides their doctor and themselves are looking after their well-being. I think we have a role to play in that.

Multinationals are losing market share. If you decrease prices how can you justify what is happening in Mexico to your headquarters? Why would AstraZeneca continue to invest in the Mexican market compared to other countries?

Let me correct one aspect of your question - decreasing prices. We are not reducing our prices. We have just been very responsible in the way that we increased our prices over time, and in today's world, we are not in a disadvantaged position because of over-correction.

You are right in that the market is shifting to generics and there is an explosive growth in that regard. At the same time, if you look at big pharma it is all relative. Look at the IMS numbers and you will see that AstraZeneca has the best evolution amongst the top 10 companies. We have the least

attrition in absolute unit terms versus the rest of big pharma and I believe that there are only two or three privileged, large pharmaceutical companies in that bracket.

AstraZeneca has a very effective commercial unit that has been able to preserve our place within the contraction of the branded, original market which means we are faring better than most.

I think the pharmaceutical industry views the way in which it operates as to how effective each one of the marketing units is in relation to their specific environment, not necessarily with a one-size-fits-all attitude.

Do you think there is going to be a shift to other markets which are growing much faster, such as China?

One must not forget that emerging markets have become, once again, a relevant fortunate growth for industry, regardless of whether you are making shoes, steel rods, or pharmaceuticals. In this particular case, we have a monster that was not around in the past, which is China. China with its vast population and the huge opportunity for lifestyle improvements to "Western standards" is an enormous potential market.

However, we are already starting to see the growth cycles of China decelerating. It would be absurd to think that China can continue to grow the way it is when their principal clients are in contraction mode. We have also seen a reduction in the level of consumption of Chinese products simply because of the economies. In this sense we have started to see China softening its growth rate, which is not necessarily a bad thing as it becomes more sustainable over time than the explosive high digit growth rate that we have seen in the past.

On the other hand, if you look at Brazil, is also going through the same cycle. Brazil did not take advantage to deflate the bubble when the rest of the world did during the 2008-2009 crisis. So today we see that Brazil has started to decelerate growth as well, partly for the same reason that China is doing so, and partly because Brazil is lagging in its competitiveness as far as internal costs for exports. Their inflation continues to be relatively high with a revaluation of the Real; you have the perfect mix to price yourself out of the market very quickly.

On the other hand, if you look at Mexico you can see an economy that has a very sustainable pace continuing to grow in the 3-4 percent bracket, which in today's world is not bad. In this game, it is not how fast or how explosively you can grow, but how consistent your growth is over time, and I genuinely believe that Mexico is very well positioned through a very rigorous monetary policy and an improving fiscal policy. You are talking about a market that oscillates between the 9th and 12th largest economy in the world. But good or bad, you are talking about a democratic, free enterprise emerging market.

So why should multinationals continue to invest in Mexico? Mexico is, and will remain, a strategic market for any industrial interest. One must not forget the cycles in Latin American history when Brazil is booming, Mexico is decelerating, and when Mexico is booming, Brazil is decelerating.

I think we had a unique period over the last few years. Between 2002 and 2007 the bulk of the Latin American economies were travelling in very favorable directions; there was Brazil, Argentina, Mexico, and Columbia with the improvement in the overall security of the country. Everybody was moving in the right direction.

Overall, Latin America as a whole will remain a core element for future growth, and I think Brazil and Mexico are poised to remain the two largest economies in the region. Mexico is probably on the

upward cycle, whereas Brazil is turning into the stabilization cycle. That does not mean it is going to be negative, but it is not going to show high growth rates.

On a more personal note, you have worked all over the world: Europe, Latin America, Middle East, and Asia. How do you like working in your own country?

Mexico is a very generous country in many regards. I think for me it has been both a privilege and a pleasure to be able to come back after 18 years expatriation, having lived in nine different countries and all five continents, and be able to share those experiences with my peers in Mexico.

Again, Mexico has been an emerging economy over the last 20 years and now we have a greater portion of our young talent coming through top international schools. Even in Mexico, we have very well qualified higher education schools and we have more MBA graduates.

The questions I ask myself are: does Europe need more talent? I don't think so. Does the US need the talent? I don't think so either. I think the talent should be placed where there may be a shortage and where it can contribute to narrow the gap in the knowledge base in order to accelerate growth.

How would you assess the talent pool today in Mexico, how easy do you find it to recruit good, committed and talented people on both the scientific and commercial side?

About 20 years ago, some of our employees were still fairly deficient in levels of formal education — namely the field force. Today you look at the field forces around industry in Mexico and you will find that the bulk of them are professionally educated.

When you compare the output of exact sciences from the national statistics institute, and some of the external analysts — the output of exact sciences in terms of engineering disciplines; life sciences; chemists; etc. — Mexico is probably top when you compare them to other environments. Yet we are still in an environment where access to that level of quality is relatively successful; it is still very competitive.

We can see the effect that it's had when you look at some of the major enterprises, such as the aviation industry, that come into Mexico and set up enormous plants, full of Mexican engineers. There is an enormous availability of talent at very significant competitive access levels in terms of the cost of these qualifications.

As far as the creativeness of Mexico, I think our culture is one that has always been very creative. That is evident in our artwork and in our street arts. Our culture stems from the Aztecs and the Mayas — there is something in our DNA. Here in Mexico we now have the ideal world combination of creativeness, responsibility and adequate formal training.

What would be your advice to a new CEO coming to Mexico?

I do not feel qualified to advise someone on running a company, but I would say that if the candidate is not Mexican, to brace themselves, because Mexico is not a 9am-5pm environment. Mexico is a very demanding market in terms of the time you need to invest in business; that is not just how many hours you spend in the office, but also how close you are to your company's structure, from the doorman to the senior management team. The closeness you need with the decision-makers, policy-makers and key stakeholders in this environment, is perhaps more intensive than in other parts of the world.

As an emerging market, we still have to remember that we have to perfect a lot of the regulatory and legal framework that governs accelerated growth. That is part of being closer to the decision-makers. I think over the last three or four administrations we have made very significant progress in terms of lowering the hurdle when the state has social interests and enterprise has personal or private sectorial interests, to a point where they actually understand each other better, as more established economies have done. We have reached the point where state and private enterprise can actually work side by side to provide solutions, rather than having opposing views as we have seen in past administrations.

Mikel Arriola from COFEPRIS told us that he was able to have an open dialogue with industry leaders and listen to them more openly. Is this the case from your point of view?

It is evident that there has been a major change in attitude and philosophies on both sides of the fence. I think the quality of public service individuals has greatly improved. I believe the ethics of the government today are light years away from those in the past. All of this is conducive for state and private enterprise to look for solutions that will be of mutual benefit to society, to the state and to the politicians, as well as to enterprise by providing a healthy platform from which to work.

How would you assess this new generation of general managers in Mexico?

You raise a very interesting concept and there are two sides to the coin.

I think a totally new, young, inexperienced set of managers may well provide an enormous degree of energy and creativity, but may lack the sensitivity to implement some of those business strategies; perhaps they are too radical. On the other hand, if you have an older management team, you may consistently end up with a high level of resistance to change.

My formula is that, if you can keep the old timers with the savvy and the wisdom, the experienced "sailors", they tend to be great guiding lights for young talent, so you get the best of both worlds. You get the knowledge and experience, with the energy and creativity and at the mid-point you find magic happens. I do believe that experience is priceless, but I also support young talent. Someone believed in me when I was only 27 and by the time I turned 28, I had almost 300 people reporting to me. Now I find myself somewhere in the mid-point between the old timers and the newcomers. I regard myself, not as a brilliant manager, but as a catalyst to generate the best of what is in both these groups of people the highly experienced and the young talent.

But we need to do more. We need to find formulas for the economy to further strengthen its job-creation capabilities. That basically means significantly updating the regulatory and legal frameworks under which the state regulates enterprise, so that without losing the rigor of justice and fairness to all, we can find the ways and means to broaden job creation to accommodate this talent.

In today's world you will find quite a lot of Mexico's top talent working abroad in more developed economies. That is because they lack, in some instances, the opportunity to evolve rapidly and apply their intellect in the local environment. You also see that in China, in India and Brazil.

So is it fun to work in Mexico? You do not know just how much. It is a fun country, and it is also a very complex environment. But then again, if it were easy, anyone would be able to do it. I thrive in that level of complexity; I enjoy it, and I enjoy building.

Why pharmaceuticals? Because, beyond the commercial challenges of companies like AstraZeneca, there is the voyage of discovery. For example; the revolutionary treatment of the major killer "hypertension" through the discovery of beta-blockers; the treatment of breast cancer (a major killer in the female population); and the treatment of peptic ulcers with the proton pump inhibitors

which have practically eradicated peptic ulcers and peptic ulcer surgery. Taking all that into consideration, it gives me great satisfaction to know that you are working above and beyond the commercial drive. Although we are in it to make an honest dollar, we are also making a very significant contribution to society, by improving the populationsâ?? health and quality of life.

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