

Interview: Alvaro Angel – General Manager, Bayer Pharmaceuticals Mexico

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Alvaro Angel, the recently appointed general manager of the pharmaceutical division of Bayer Mexico, provides insights into the rapidly evolving local pharma market, and documents Bayer Mexico’s ambitious growth strategy; with the affiliate already standing out as one of the most important of the group at a global level.

You took over the helm of the pharma division of Bayer Mexico in January 2016, after having headed Bayer’s footprint in Venezuela, Ecuador, and Peru over the last ten years. What have been your first impressions when joining the Mexican affiliate?

First, Bayer’s footprint in Mexico is particularly impressive. Our affiliate’s pharmaceutical division stands as the fifth largest pharma player in Mexico in terms of market share, while Mexico moreover ranks among the ten most important countries within Bayer’s global strategy.

I also noticed some very interesting market trends: the Mexican healthcare eco-system was evolving, especially the private market, which was still undergoing profound transformation that would only accentuate in the upcoming years. In Mexico, big pharmacy chains are taking control of the retail market, while recent acquisitions occurring in the retail sector further strengthened its consolidation. Within the the next five years, I expect four or five big pharmacy chains will control around 80 percent of the entire retail business, while in 2016 they already make up 66 percent of the total value of the Mexican retail market (according to IMS Health). Furthermore, these pharmacy chains are increasingly developing their own private labels, and – according to recent Funsalud research, 60,000 doctors now provide consultations and issue prescriptions at these pharmacies’ point of sales. As a result, in 2015, more than 320,000 prescriptions per day were issued in these consultation rooms, which is higher than the total number of prescriptions issues in IMSS and ISSSTE’s health centers. Patients usually attend these pharmacy consultation rooms for simple and common illnesses, such a headache or stomachache. Nevertheless, we see that for these specific diseases, pharmacy chains’ private labels now make up most of the total prescriptions.

As a result, in Mexico, three different players are now competing in the private sector: pharmacy chains – private labels, generics and innovators. Although the retail market grew 7.1 percent over the past 12 months (IMS Health), original brands’ growth didn’t exceed two percent. We thus

understand that generics and private labels take the lion's share of the Mexican private sector's growth, by displaying growth rates comprised between fifteen and twenty percent per annum.

In the public sector, the three main social security institutes – IMSS, ISSSTE, and Secretaría de Salud – are particularly keen to see their patients accessing life-saving treatments, but they also face increasing budget pressure. Over the six months, the current government unfortunately released two health budget costs that amounted to around USD 500 million in total. As a consequence, over the last two and half years, only 15 out of the 213 molecules that were initially approved by Cofepris, Mexico's regulatory authority, have ultimately been registered for use by IMSS and its 70 million beneficiaries. In 2016, ISSSTE, the social security institutions covering almost 13 million public-sector workers, has so far only included two new molecules in its registries. Considering the budget pressure they face, these institutions also go for the cheapest options as soon as therapeutic alternatives reach the Mexican market.

[Featured_in]

We acknowledge these institutions have to solve a tricky equation to ensure Mexicans can further access innovation while respecting their budget limits. In this regard, this situation also provides pharmaceutical innovators with a broadened responsibility to generate the right market access approach that can favor innovation access. The social security institutions are increasingly open to consider innovative market access models to provide their beneficiaries with life-changing treatments. As a result, companies that can offer integrated services or implement risk-sharing models may hold a competitive edge in their negotiations with public partners.

Small, innovative biotechs implanted in Mexico are particularly keen to experiment innovative access models, tailor-made to the specific processes of each social security institution. Nevertheless, these companies usually hold a portfolio comprising only a few treatments. Isn't it more challenging to become creative and innovative for Bayer, which boasts a more substantial width of product portfolio?

To fulfill this objective, we indeed have to radically change our market approach. The current deadlocks to innovation access imply that old ways to bring products to the Mexican public market may not work anymore. The old model, where you only had to prepare a good reimbursement dossier with pharmaeconomics studies before simply asking for a given price becomes now completely irrelevant.

In 2015, Bayer Mexico was still essentially focused on the private market, although with the launch of our innovative products we are shifting our focus to the public sector. This year, we started to tremendously strengthen our market access capacity and implement a cross-functional structure. To be successful in the institutional market and design more innovative market access models, we indeed believe a greater integration of the medical, marketing and market access departments becomes absolutely crucial. We have to become more efficient and more integrated in our communication with public partners: for 2016 alone, we already have six molecules for which we currently negotiate to obtain a reimbursement code from the General Health Council [*the final approval step before starting to negotiate with social security institutes in Mexico, e.d.*]

We however already boast some satisfying achievements: we recently obtained a reimbursement code for Wetlia® (the market name of Eylea® in Mexico, to treat neovascular wet age related macular degeneration (WAMD)), while in 2016 Xarelto® (our oral anticoagulant) was included in IMSS registries. Our efforts are already paying off and we are definitely gathering momentum, which renders me particularly confident in our ability to get the six molecules aforementioned soon

approved by the General Health Council before starting to negotiate to get them accessible at both IMSS, ISSSTE and Secretaría de Salud.

Bayer recently launched Wetlia®, Stivarga®, Xofigo®, Jaydess®, Adempas® and Xarelto® in the Mexican private market. In the meantime, we see that Cofepris recently approved four new indications for Wetlia®, two new presentations of Sivextro® and granted approval to Bayer's new contraceptive patch Apleek®. In this plethora of new market authorizations, on which treatments will you concentrate your efforts in the upcoming months?

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In October 2016, we will launch in the private, retail market our new transparent, low-dose contraceptive patch Apleek®, which will be followed by Sivextro® (treatment of acute bacterial skin and skin structure infections) in October 2016. In the meantime, we will submit these two products' dossiers to the General health Council to obtain a reimbursement code.

Regarding Wetlia® (for wet AMD), this treatment displayed 151% growth in 2016 in the private market, and we already managed to get a reimbursement code for the inclusion of this treatment in PEMEX's specific social security scheme [*PEMEX being the Mexican state-owned petroleum company, e.d.*]. Our biggest challenge for the next six months will be to ensure this treatment finally is included in the registries of the main social security institutions, IMSS, ISSSTE and Secretaría de Salud.

With regards to Stivarga® (colorectal cancer), Xofigo® (prostate cancer), and Adempas® (hypertension CTEPH), the General Health Council didn't grant yet a reimbursement code. This unsatisfactory situation leaves us with no choice but to work closely with the Council to see how we can present new and better-adapted submissions. We notably plan to enrich our current reimbursement dossiers with specific, local data collected among the Mexican patient population through the private sector, and then relaunch these treatments' reimbursement process before the end of the year.

Bayer is active in cardiology, oncology, gynecology, hematology and ophthalmology. What is the relative performance of these therapeutic areas in Mexico?

In 2015, Bayer implemented a project called "LatAm 2020", which aimed at reorganizing our pharma division around five therapeutic areas.

In Mexico, our most important sales driver still remains the EP segment, which essentially comprises mature products and makes up 67 percent of the total sales of the Mexican pharma division. Looking at oncology, our third largest therapeutic area, sales are notably driven by Nexavar® (kidney cancer), which has been growing 22 percent in 2016. In this field, Bayer proudly stands as the fastest-growing company in Mexico. In Cardiology, our flagship product Xarelto® is growing 25 percent in 2016 and we already hold a 49-percent market share in this therapeutic area. In gynecology, we can notably rely on our birth control treatments Mirena® and Jaydess®, which are doing very well in Mexico.

Looking specifically at innovative products, the growth is mainly driven by Xarelto® and Wetlia® (151 percent growth in 2016), while Kogenate® (to replace clotting factor that is missing in people with hemophilia A) and Betaferon® (multiple sclerosis (MS)) are currently facing difficulties in the public sector because of an heightened level of competition in their respective market niches. In the meantime, we are currently designing innovative market access models to be submitted to social security institutions, in order to accelerate the reimbursement process of these hematology

treatments.

Most of the treatments I aforementioned have been launched over the past few years, and the vast majority of them already have already been extremely successful – despite being only available in the private market. Our objective is now to find ways to sustain and expand this growth over the upcoming years by making these treatments accessible in the public sector.

In July 2016, Bayer’s pipeline displayed 18 compounds in phase III clinical study, mostly in oncology and cardiovascular diseases. Considering the company’s pipeline and Mexico epidemiological profile, what treatments are you most excited to bring to Mexican patients?

Oncology and Cardiology will obviously remain crucial therapeutic areas in Mexico. Furthermore, we see Mexico faces dramatic health issue with regards to birth control, as the country unfortunately displays one of the highest rates in the world for teenage pregnancy.

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At Bayer, we hold a complete array of therapeutic solutions for birth control, from oral, injectable, intrauterine devices to now our new transparent patch Apleek®. In the upcoming months, we will moreover launch in Mexico Jadelle®, our contraceptive implant. As a result, we are currently the only international company in Mexico that can offer to the government a comprehensive set of solutions to tackle this dramatic, worrying health issue. Looking at our current development pipeline, this is clearly a therapeutic area, alongside oncology, where our new innovative products can significantly improve health outcomes for Mexican patients.

Laura González Molero, President of Bayer Pharmaceuticals for Latin America, who recently left the company, highlighted that in 2015 Mexico represented 26 percent of the total sales of the region, following closely Brazil (31 percent of the region’s sales), although the latter is one and half more populous than Mexico. How do you explain the significance of the Mexican market for Bayer?

Mexico has always been a very important market for Bayer. Furthermore, the strategy that Bayer Pharma has been following in Mexico for many years has proved being extremely successful, especially in the private sector.

In the private sector, our strategy in Mexico has been mainly relying on a substantial and well-trained sales force that actively worked with physicians across the Mexican territory. As Mexican private sector is becoming evermore competitive, we now need to complement this asset with multi-channel activities, virtual representatives, as well as an optimized commercial trade approach.

In May 2016, Bayer was ranked as the pharmaceutical company displaying the best and the strongest reputation among the entire industry according to a study conducted by the Reputation Institute. As head of the pharma division in Mexico, what will be your key points of focus and the philosophy you want to convey to your teams to ensure such a positive image is maintained in Mexico?

In this regard, continuously training our overall teams, and not only our sales force, is absolutely paramount to ensure we can maintain such a reputation and remain consistent in the way we operate with all our partners and clients across the entire value chain. Furthermore, it should not be forgotten that resources allocation plays a major role in providing your employees with the ability to outperform and exceed your partners’ expectations, so we have to ensure our collaborators hold

the resources to exceed our partners' expectations. Finally, establishing a clear strategy among the entire affiliate is the only way to guarantee all our collaborators are driven by the same long-term objective, on a daily basis.

In 2016, we have been fine tuning our strategy, and I can assure you all our employees now understand and share the same vision: maintaining our strong position in the private market to generate the cash flow that will allow us to be evermore successful in the public sector and include our molecule as swiftly as possible within the institutional sector.

In Mexico, Bayer already stands as a top five player. What is your growth vision for the affiliate?

We want to maintain our position among the top five by continuously displaying double-digit growth rates. We probably won't be able to forever boast such growth rates in the private sector, but we expect that by improving our performance in the public sector, we can reach this overall double-digit growth rate objective for the overall pharmaceutical division. Finally, we want to continue to outperform the Mexican pharmaceutical market's growth over the coming years.

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