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16.11.2022

Tags:

LatAm, Argentina, BMS, Strategy, Access, Clinical Trials

Florencia Davel, head of LatAm operations for Bristol Myers Squibb (BMS) looks back on a successful four years in position, shaping the regional organisation into a true biopharma player in line with a global strategy shift. Davel also casts her eye over the market access scenario in LatAm, why BMS is choosing to situate clinical trials in the region, and how she hopes to capitalise on abundant opportunities to better serve patients in the coming years.

After four years in position as VP for LatAm at BMS, what are the key points on your agenda today?

There are many things on my agenda, but prioritisation is the first one. It is the only way to deal with the complexity inherent to the LatAm region. Externally, we must manoeuvre in an ever-changing environment to bring more new medicines to more patients more quickly.

As a leading biopharma company, we research, develop and bring breakthrough medicines to patients to treat challenging diseases as cancer. Access to innovation in the region is, as well, a

priority in my agenda, by securing partnerships with public systems and health institutions across the region. Working together with public systems is central to our strategy since we are pursuing the same objective: creating sustainable health systems that allow the right patient to access the right medicine at the right time.

Also within my priorities are the well-being and development of my teams and the maintenance of an engaging, diverse and inclusive workplace. To deliver for patients we need, and I am certain we have the best people in the industry. Since Bristol Myers Squibb shifted its strategy in 2017 BMS to a biopharma portfolio we have had to evolve the capabilities of our people to support this. Ensuring that the organisation has the right culture, capabilities, and people in place is â?? and will remain â?? crucial.

To meet our objectives, we are prepared to face the current challenges such as creating a sustainable pricing strategy while navigating the currency inflation and devaluation that lead to budget constraints. In addition, the protection of intellectual property in the region remains an important topic that we need to continue working on, to encourage investments and the continuous development of innovation.

Why does Bristol Myers Squibb base its LatAm leadership in Argentina?

Bristol Myers Squibb has five affiliates in LatAm: Argentina, Mexico, Colombia, Chile and Peru. Argentina has always been the companyâ??s regional base, that hosts most of the regional teams that provide support to the market. My predecessors have all been expats and I am the first Argentinian to hold this role.

How would you define the openness of governments and regulators in LatAm to innovation in LatAm? Are they receptive to the pharmaceutical industryâ??s arguments about new medicines as an investment rather than a cost?

It is a mixed bag. There are great examples of countries in LatAm where the doors are open to productive dialogue around innovation and where there is full alignment on the need to provide more and better patient access. The challenges we must face depend on the market and cover not only discussions around products being commercialised but also clinical trials. Greater clinical trial numbers will lead to faster innovation adoption and greater inward investment, which is firmly in line with the stated agendas of most LatAm governments. There has been good progress on this front in Mexico, Colombia, Argentina, and Chile for example, although we are still struggling in markets such as Peru.

Empathetic dialogue and an understanding of our shared goals, and the value that innovation brings to health systems are critical, as is facilitating enabling infrastructure, creating better access to institutions, and fostering a holistic view of diseases from prevention to diagnosis and treatment. Moreover, we work with governments to help them understand the pharma industryâ??s impact on productivity and employment; for every industry employee, we generate indirect employment of around 1.7, almost doubling the employment rate.

Governments in LatAm often seesaw between left and right, but do the conversations you have with public sector stakeholders differ much depending on the current

administrationâ??s political stripes?

Collaboration breeds credibility and transparency, which are the basis of any strong relationship. One challenge is maintaining an ongoing dialogue on multiple issues, which is vital to building sustainable healthcare systems.

The COVID-19 pandemic put the importance of health under the spotlight and facilitated dialogue and between different stakeholders, from industry to government as well as trade associations, chambers of commerce, scientific societies, academia, and patient organisations. Of course, openness levels differ by country, but there has been a general trend towards inter-stakeholder collaboration in the past few years. I saw this clearly in my role as chair of the Latin American Federation of the Pharmaceutical Industry (FIFARMA) and continue to do so today.

How long do patients in LatAm have to wait to access innovative medicines compared to their counterparts in other regions?

Access times tend do tend to be faster in the private sector, which all LatAm markets have to varying degrees of strength. In the public sector, timelines can be slow which means that patients are treated later in their disease progression, lessening the potential for innovative medicine to have an effect, and having a direct negative impact on the productivity of the patient, their caregiver(s), and the country as a whole.

A recent FIFARMA/IQVIA study showed the length of time that patients in LatAm were waiting to access new medicines following US Food & Drug Administration (FDA) or European Medicines Agency (EMA) approval, with patients in Argentina and Colombia waiting 900 days, while those in Peru must wait for over 1000 days. This clearly illustrates the access challenge and the opportunities as well ahead of us and why shortening regulatory approval and access timelines is a key priority.

In terms of access, Colombia has shortened its timelines, but its regulatory agency still takes too long to approve new commercial medicines as well as clinical trials. The same is true of Mexico. Regulatory reliance, whereby the national regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another national regulatory authority or trusted institution in reaching its own decision, could be crucial in solving this problem.

Bristol Myers Squibb acquired Celgene in 2019, signalling a further step in the companyâ??s transformation into a fully-fledged biotech. What has been the impact of this deal in LatAm?

Prior to 2019, Celgene had affiliates in Brazil (which is not under my direct responsibility) and Mexico, which have now been integrated into the companyâ??s operations. Celgene operated via local representatives elsewhere in LatAm, and after a one-year project we were able to transfer Celgeneâ??s portfolio from the distributor to Bristol Myers Squibb, while keeping our distribution agreement in 12 markets where we do not have commercial offices. All this has given the combined company a strong haematology footprint in LatAm and we also plan to begin expanding our immuno-oncology portfolio.

Bristol Myers Squibb LatAm has seen significant growth since 2019 because of the Celgene acquisition, particularly in Mexico where we have a significant haematology business. Moreover, the integration journey was an amazing experience and helped us combine Celgeneâ??s entrepreneurial spirit with the process-driven big biopharma mindset we have at Bristol Myers

Squibb. Working with local representatives has also opened our eyes to alternative delivery models and the value of leveraging their local knowledge and experience to expand access to innovation.

How has the company been performing in the region more generally in the last few years?

Bristol Myers Squibb LatAm has been able to generate outstanding double-digit growth year-on-year for the last five years. The company, which now has a headcount of 500 in LatAm, has had 20 new approvals between new indications and new products during the last half decade and is expecting six new products to be approved in the next two years. Our clinical trial investments have risen by 20 percent in the past year, and we will reach more than 15,000 patients with our treatments by the end of 2022.

Another important indicator of our strong performance is the number of Bristol Myers Squibb LatAm staff who have taken on positions in key international markets such as the US. LatAm is clearly a talent hub, in part thanks to our peopleâ??s ability to navigate uncertainty and complexity, and the company is keen to open the door for them to take on new roles globally.

How important is LatAm as a clinical trials hub for BMS globally?

LatAmâ??s clinical trials operations are significant, and the company has invested USD 200 million in this area over the last five years. More than 2,000 patients are receiving treatment with BMS medicines via clinical trials in more than 484 centres in the region, with major hubs in Argentina, Mexico, Colombia, and Chile.

Our centres in LatAm participate in Phase I and early-stage trials and BMS has become a top enroller in breast cancer in Mexico. Moreover, the physicians with which we work are authors of key publications around these trials. As mentioned previously, our clinical trial investments in the region grew by 20 percent last year, and we foresee this trend continuing.

Two of the companyâ??s five global diversity and inclusion commitments, launched in 2020, are directly related to clinical trials. These two commitments â?? addressing health inequities and building more clinical trial diversity â?? fit perfectly with our work in LatAm, where there is significant health inequity which can be addressed through clinical trials as well as a diverse multi-ethnic population.

Is there sufficient enabling infrastructure in place in LatAm for BMS to continue to expand its clinical trial operations in the region?

Many LatAm countries â?? especially those where we have clinical trial hubs â?? stand out from other emerging markets for the high level of infrastructure they have in place, particularly in the private sector. However, BMS wants to increase the participation of public sector hospitals in clinical trials and to this end in Argentina we have an award-winning initiative known as the ESSENCE project, recognized in the companyâ??s Innovation Tournament as a game changer. This initiative aims to address both our health equity and clinical trial diversity commitments by ensuring that the supporting infrastructure is in place for public sector hospitals to participate in clinical trials.

What have been the most significant milestones in your two decades with Bristol Myers Squibb and what are you most excited about looking forward?

The launch of our biopharma strategy in 2017 was a big milestone, as was the launch of a new generation of treatments for challenging diseases. We focus on innovations that drive meaningful change as we have one of the most diverse and promising pipelines in the industry. Iâ??d like to highlight that Bristol Myers Squibb has been a pioneer in the immunooncology field, bringing to LATAM the first IO therapies to treat different types of cancer.

We now have a psoriasis product in the pipeline which stands to be yet another breakthrough, as well as CAR-T cell products that have a very promising future. Our job is to help prepare LatAm to be able to adopt these upcoming breakthroughs, not only in terms of budget, but also infrastructure, clinical trials, and sufficient patent protection.

Do you have a final message for our global audience?

I define LatAm as the land of opportunities and my motto is that every crisis leads to opportunity. We have a diverse population, strong healthcare systems across the region, and our approach is to work collaboratively with other stakeholders to address what matters: bringing more innovation to more patients more quickly. Through health economic assessments, we aim to pinpoint how best to incorporate new medicines into a countryâ??s formulary and health system, thereby creating a more sustainable overall system that treats patients as quickly as possible, lessening the burden on them, their caregivers, and their country.

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