Yaneth Giha – Executive Director, FIFARMA

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Yaneth Giha of FIFARMA – the leading association for the innovative pharmaceutical industry in Latin America – gives a bird's-eye overview on some of the key trends in LatAm healthcare, from regulatory and access challenges to the impact of the COVID-19 pandemic, the region's potential as a clinical trials hub, and the crucial importance of inter-stakeholder collaboration.

Could you introduce FIFARMA and its mission?

FIFARMA is the Latin American Federation of the Pharmaceutical Industry, created in 1962. While the association is now over 60 years old, it has picked up a new energy and momentum over the past decade. Our 27 members include 16 of the biggest global pharmaceutical R&D companies, but also 11 national R&D-based industry associations, including AFIDRO in Colombia, AMIIF in Mexico, and Interfarma in Brazil. We draw on the national-level insight that these local associations provide in navigating the dynamic Latam region.

While LatAm is constantly changing, our basic aims remain the same: to promote innovation and innovative ecosystems for the benefit of the region. As many other actors in the region, we want quality healthcare for all Latin American patients, and we are convinced that innovation is and will be a key player in the social and economic development of our region.

FIFARMA's work focuses on three elements. The first is the development and financing of studies and reports in partnership with academic institutions around the world. These help us better

understand the challenges in LatAm and how they can be addressed. One of our recent studies was developed with the WifOR Institute in Germany and another was done with IQVIA on a Patients Waiting to Access Innovative Therapies (WAIT) Indicator, similar to those published by IQVIA and the European Federation of Pharmaceutical Industries and Associations (EFPIA) in Europe.

Secondly, we work closely with national governments. Developing data and analysis alone is not enough; we need to take action. For example, the WAIT indicator gives a lot of insight into what we should be doing; some countries need this data to strengthen their regulatory systems while others might use it to improve access through the implementation of flexible models such as managed entry agreements (MEAs).

Finally, we work with other stakeholders in the region, such as some of the non-state actors within the Pan-American Health Organization (PAHO). We also have an ongoing project with several universities in the region regarding health as an investment. Having previously worked in the Colombian government for many years, I have learned that no solution ever comes from a single actor. Instead, we need to create solutions by working collaboratively and bringing capacity, knowledge, understanding, and resources together.

How does FIFARMA's work differ from that of the EFPIA in Europe or PhRMA in the US? Are there any region-specific challenges to representing your members in LatAm?

Definitively, our sister associations like PhRMA and EFPIA, have projects and initiatives aligned to their needs and context, however, I'm firmly convinced that our goal is the same: improve the patients' lives as well as achieve better results for our regions. Our purpose is to work in an articulated manner and align strategies and efforts to seek innovative solutions to address joint challenges. Currently, there are many projects where our work is complementary, for example, we work closely with PhRMA on Intellectual Property (IP) programs to strengthen our IP systems and accelerate the innovation in the regions. On the other hand, the engagement and extensive dialogue with EFPIA was instrumental to develop the FIFARMA WAIT Indicator for LatAm. These are the proofs that teamwork is the key to achieving better results.

There are, however, challenges that are more pronounced in LatAm than in Europe or the US. One example is the insufficient level of public health expenditure in the region, as shown in the recent WifOR study. PAHO set an objective for all LatAm countries to spend at least six percent of their GDP on public health, but this has yet to be achieved. The OECD average is 5.8 percent, while the strongest countries in LatAm on this front are Chile and Argentina, which spend 4.9 percent,

followed by Colombia (4.1 percent), Brazil (3.8 percent), Peru (3.3 percent), and Mexico (3.1 percent). Expenditure needs to be raised, as does awareness of the importance of health as an investment.

The second biggest challenge, also touched on in the WifOR study, is insufficient healthcare capacity across the region. This covers everything from doctors to nurses, intensive care units (ICUs), and digital health capabilities. During the COVID-19 pandemic, this lack of digital infrastructure was laid bare and those living outside of cities found it much more difficult to access care. Argentina is our region's best performer on this front, followed by Brazil, but there is still a lot of work to be done in other countries. These indicators show that Latam was not well prepared for the pandemic.

The final challenge is related to patient access to innovation. As the IQVIA WAIT Indicator shows that the average delay between marketing authorization and patient access varies between 1.5 years and more than 3.5 years. For example, it takes around 1.294 days in countries like Colombia and 941 days in Argentina for new innovations to get approved, registered, and made available to patients following approval from the US Food & Drug Administration (FDA) or European Medicines Agency (EMA).

COVID shone a light on the barriers, roadblocks, and inadequacies in healthcare systems around the world. Do you see the pandemic as a potential turning point for LatAm stakeholders in terms of healthcare spending and prevention?

The pandemic raised awareness of the importance of health and led to governments in many LatAm countries putting healthcare much higher on their agendas. The challenge now is making sure that the lessons learned over the past two and a half years are not forgotten. Healthcare needs to remain being seen as an investment, especially given the fact that we will probably face more pandemics in the future.

The WifOR study showed a lack of capacity in many aspects of healthcare in our region and our hope is that the plans that were developed during COVID are put in place and implemented.

LatAm is a huge region containing both middle-income and low-middle incomes countries as well as varying levels of public and private healthcare. Is it therefore feasible to rollout region-wide initiatives, or does a country-specific approach always

need to be taken?

Both region-wide *and* country-focused approaches are valid as there are both common and specific challenges in LatAm. Common challenges include the need to increase capacity and awareness of health as an investment, to reduce levels of inequality and high level of out-of-pocket spending (although Colombia has made the most progress on that front).

However, access challenges are more pronounced in Brazil, Mexico, and Chile, while in Colombia the issue is on the regulatory side of things.

This kaleidoscope of challenges means that FIFARMA has to work both on a continent-wide level on general trends as well as on a national level with local associations and other in-country stakeholders.

LatAm is also characterised by political and economic volatility, often experiencing dramatic swings to the left or right between administrations. How does that affect FIFARMA's work?

The pandemic showed us the importance of robust and sustainable healthcare systems that are focused on the patient's wellness, regardless of the political agenda in the countries. People's health is beyond ideologies and one of the key challenges, not only for FIFARMA, but also for government stakeholders, local associations, and society in general, is to identify opportunities to work together to improve access, availability, and innovation. There are different strategies that can be implemented jointly with the countries to improve the conditions of patients in LatAm without neglecting the sustainability of the health systems in the region. One of these strategies is value-based and flexible access models. These models accelerate access to patients and ensure the financial sustainability of health systems.

FIFARMA's work has a particular focus on conversations and establishing communication bridges with government stakeholders to focus the attention on patients' lives and be an active actor in solutions for the region.

Have you seen an increased willingness to engage in conversations around pay-for-performance models and managed entry agreements for medicines in LatAm?

Yes. One lesson learned in our region is the need for value-based and flexible access models that accelerate access to patients and ensure the financial sustainability of health systems. FIFARMA has been working with Management Sciences for Health (MSH) on these types of models in several LatAm countries, most notably Colombia and Peru, and has plans to add more countries to this list in 2023.

The first reaction is always positive because government stakeholders see these models as an opportunity for healthcare systems and for patients, as do we. However, it should be remembered that these models are relatively new in our region and even if there is good momentum and a willingness to embrace them, we also need to create capacity, norms, and regulations around them.

Clinical trials are a key part of the access conversation; how would you assess LatAm's progress towards becoming a clinical research hub and what impact would this have on drug development, access, and patient outcomes?

LatAm can be a great place for clinical research and in many aspects *is already a great place for clinical research*. This region has an ethnically diverse population, strong doctor-patient relationships, and great clinical research centres, all of which are increasingly attracting the eye of our member companies when choosing where to base their clinical trials.

It is estimated that ten percent of clinical research worldwide is done in LatAm, predominantly between Brazil, Argentina, and Mexico and where IQVIA estimates the pharmaceutical industry has made investments of approximately USD 980 million. Four years ago, Argentina defined clinical research as a governmental priority, catching up to Brazil and Mexico which have long had a strong footprint thanks to their large populations and local markets. Colombia and Chile are also becoming more significant, making up 20 percent of the LatAm total, with other countries accounting for the remaining ten percent.

However, one challenge is making our regulatory systems and the regulations surrounding clinical research more attractive. For example, in Colombia, the regulatory agency was previously taking around six months to approve a clinical trial. Then it moved to around two months, which sends a strong message, as did Argentina's move to change its regulation four years ago to incentivise clinical research investments and make the process more efficient.

The ethics commissions that have sprung up can also create obstacles, but these commissions are now improving and have a better understanding of how to create solutions.

While Europe can count on a single regulator to approve medicines across the continent – the EMA – Latin America lacks such a body. What progress have you seen around regulatory reliance and leapfrogging on the work of leading regional regulators to get medicines to patients more quickly?

Many of the national agencies in LatAm have shown good progress in the last few years. ANVISA of Brazil is still the leading agency in the region, thanks to its openness, ability to work with other stakeholders, and awareness of global industry trends. Argentina's ANMAT has also made some significant steps forward in the last few years. However, there is room for improvement at INVIMA (Colombia) and COFEPRIS (Mexico). This represents a fantastic learning and growth opportunity, in areas such as regulatory reliance and good regulatory practices.

For FIFARMA's part, we are ready to collaborate in the process of increasing capabilities.

In many European countries, the approval and rollout of COVID diagnostics, treatments, and vaccines forced regulatory bodies to adopt greater speed and agility – was that the case in LatAm as well? What are the main lessons to be learned from this process?

When the COVID-19 pandemic hit Latin America in late February 2020, most governments moved quickly to provide swift and decisive responses to control the outbreak and tackle its economic and social impacts. Nearly 70 percent of the hemisphere's population is fully immunized as of the end of June 2022, because countries and regulatory agencies worked hard to approve vaccines very quickly. A number of agencies have now committed to permanently maintaining many of their new business engagement functions and we should encourage all agencies in the world to implement the same.

Furthermore, one of the most significant achievements of pandemic medicine was the ability to rapidly assess, test, and monitor the general population. Without a doubt, this is a trend that we, as a federation, should encourage in order to provide follow-up care to patients in any therapeutic area and, as a result, accelerate access to a sustainable, efficient, and innovative healthcare

system.

What is your final message to PharmaBoardroom’s international audience?

We need to come together and work for better health systems around the globe. Patients have the right to the best health services, the best quality, and the best therapeutic solutions whenever they need it. That should be the objective of every human being, but especially everyone that works in health. The solutions to the complex challenges we are facing will only be found through working together for the benefit of all.

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