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Regulatory reliance is about trust, not surrendering sovereignty.

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*Yaneth Giha, Executive Director of FIFARMA, has transformed the organisation from a traditional trade association into a strategic platform for advancing healthcare access in Latin America. The first woman to lead FIFARMA, she drives evidence-based solutions, multi-stakeholder collaboration, and regulatory reform, positioning the region as a rising force in global pharmaceutical innovation and clinical research.*

**How has FIFARMA evolved its strategic approach to creating value in the Latin American pharmaceutical landscape?**

Every organisation possesses its evolutionary trajectory, and FIFARMA currently operates within a period of unprecedented momentum and transformation. We have progressively refined our understanding of value creation through our regional umbrella structure, which provides extraordinary opportunities to advance healthcare access for innovative medicines across Latin American markets.

While our fundamental strategic priorities have not changed, we have identified three distinctive methodologies that significantly amplify our impact.

The first pillar centres on generating comprehensive data, studies, and strategic reports. Our recent achievements include the Biopharmaceutical Competitiveness and Investment Report, developed in partnership with Pugatch Consilium. We have also produced the fourth iteration of our FIFARMA WAIT Indicator with IQVIA, accompanied by our inaugural Root Causes Analysis Report, which

analyses access timelines for innovative medicines in 10 countries of Latin America, highlighting opportunities and challenges to timely and equitable treatment availability.

Investing in health is investing in life. Thatâ??s why we developed the Socioeconomic Burden of Disease study with the WifOR Instituteâ??to show the links between health, productivity and economic growth, and to highlight the critical role of health investment as a driver of stronger economies and healthier populations.

Currently, we are collaborating with Duke University on a comprehensive health budget analysis for Latin America, and we recently launched our clinical research study conducted by CIDI Salud, alongside our Good Regulatory Practices Observatory with INNOS. This evidence-based approach fundamentally transforms engagement quality, enabling more productive dialogue that drives meaningful policy advancement.

The second strategic pillar involves creating and consolidating platforms for multi-stakeholder collaboration. These forums facilitate convergence among diverse regional actors to advance critical healthcare agendas. Our inaugural FIFARMA Annual Summit in Mexico exemplified this approach, bringing together over 200 participants, including regulators, government officials, patient advocates, academic institutions, and pharmaceutical companies. This comprehensive representation enabled constructive dialogue on the regionâ??s most pressing healthcare challenges.

Additionally, we conduct Innovation Daysâ??country-specific events addressing localised challengesâ??and Innovation Missions, where we facilitate exposure to cutting-edge innovation ecosystems in Boston and Washington. Our annual Latam Health Champions Call further reinforces our commitment to creating meaningful dialogue platforms.

The third strategic area leverages the first two pillars by establishing convergent connection points. We conduct targeted workshops and introduce international best practices, providing concrete examples that accelerate progress across our strategic priorities.

These methodologies represent our evolved approach to delivering enhanced value to a region with substantial unmet healthcare needs through evidence generation, platform creation, and comprehensive stakeholder connectivity.

**What were the primary insights from FIFARMAâ??s inaugural Health Summit, and which challenges do you consider most critical for improving healthcare access across Latin America?**

The summit represented a transformational milestoneâ??a realisation of our vision to convene all healthcare system stakeholders across Latin America within a single forum. The eventâ??s significance extended beyond attendance figures; we are proud to know that we were able to bring together so many stakeholders and facilitate a constructive, solution-oriented dialogue among government officials, regulators, patients, academia, and industry representatives.

Five critical insights emerged from this gathering. First, Latin America must reconceptualise health as a strategic investment rather than an expenditure. Extensive research validates the health investmentâ??s strategic importance for sustainable development, yet this perspective requires broader regional adoption.

Second, scientific advancement alone proves insufficient without robust regulatory frameworks and aligned health systems. These components must operate in synchronisation to deliver optimal health

outcomes and innovation access for patients.

Third, stakeholder collaboration remains essential for building resilient health systems capable of meeting patient needs. This collaboration transcends traditional boundaries and requires genuine commitment from all participants.

Fourth, innovation generates meaningful impact only when it reaches those who require it most. Innovationâ??s transformative potential for individuals and society can only be realised through effective access mechanisms.

Finally, platforms such as our Health Summit are indispensable for regional progress. Enhanced dialogue, supported by comprehensive data analysis, enables evidence-based conversations that illuminate our current position and identify pathways for advancement.

However, substantial challenges persist. The fundamental obstacle involves achieving genuine collaborative commitment among all stakeholders to define collective actions and honour individual responsibilities for required progress. Success in this area would create a foundation for addressing additional regional challenges.

**Have you observed meaningful progress in regulatory and governmental understanding of collaborative healthcare innovation over recent years?**

Progress varies significantly across the region, though encouraging developments are evident. The fundamental challenge of recognising health as an investment rather than a cost persists across all countries, representing a universal obstacle requiring sustained attention.

Nevertheless, stakeholders increasingly recognise that collaborative approaches are essential for overcoming regional challenges. Each stakeholder contributes distinct expertise and knowledge, and the convergence of these capabilities enables transformative outcomes.

**The 2025 WAIT Indicator reveals that patients wait 5.6 years for new treatments, with only 33% of global medicines available in Latin America. What factors drive these concerning metrics?**

Our FIFARMA WAIT Indicator 2025, launched during our FIFARMA Annual Summit and subsequently presented in a regional webinar, demonstrates how comprehensive data facilitates meaningful stakeholder engagement. The indicator covers over 80% of innovative medicines launched recently across multiple therapeutic areas, providing a substantial analytical foundation for policy discussions.

The 5.6-year average waiting period reflects two primary systemic challenges. First, regulatory approval processes require approximately 3.5 years on average across regional agencies. This duration represents a significant improvement opportunity, particularly through enhanced regulatory reliance mechanisms.

Second, an additional 2.5 years typically elapse between regulatory approval and patient accessibility. This post-approval delay reflects multiple factors requiring country-specific analysis.

Regulatory agencies face capacity constraints and resource limitations that impact approval efficiency. Health Technology Assessment bodies across Latin America similarly experience

resource constraints and operational challenges that limit their effectiveness. Enhanced tools, capabilities, and resources are essential for meaningful progress.

The economic dimension presents another critical challenge. Many Latin American countries continue investing less than 6 percent of their GDP in public health, falling short of the WHO and PAHO minimum recommendations established years ago. When combined with political volatility and fragmented healthcare systems, these factors create substantial barriers to progress.

The WAIT Indicator serves as a catalyst for country-specific stakeholder dialogue aimed at developing tailored solutions. Rather than prescribing universal solutions, we provide comprehensive data, exemplary practices, and strategic inspiration to facilitate locally developed approaches to identified challenges.

**How are regional regulatory agencies advancing reliance mechanisms and expedited approval processes? Are there standout success stories worth highlighting?**

Regulatory reliance represents an area with substantial improvement potential, as indicated by our WAIT Indicator findings. The foundation for progress was established in 2018 when the PANDRH Networkâ??the Pan American Network for Drug Regulatory Harmonization, coordinated by PAHO with FIFARMA participationâ??developed regional guidance incorporating reliance principles. This initiative provided crucial groundwork for regional reliance discussions.

The 2021 WHO Good Reliance Practices Guideline further advanced the framework by providing countries with comprehensive guidance for implementing reliance mechanisms. While Latin American countries have expressed interest in regulatory reliance, implementation depth varies significantly across the region.

Some agencies have developed reliance capabilities for specific regulatory functions, but evolution rates differ substantially between countries. Current requirements include enhanced technical capacity, mutual trust developmentâ??since reliance fundamentally represents a trust mechanismâ??and transparent, efficient implementation frameworks tailored to national contexts.

A critical misconception involves the relationship between reliance and regulatory sovereignty. Countries sometimes perceive reliance as compromising regulatory independence, when in reality, reliance mechanisms recognise other agenciesâ?? work while maintaining national regulatory authority. This conceptual evolution is essential for regional progress.

Anvisa exemplifies successful reliance implementation, having pioneered Latin Americaâ??s first regulatory reliance guidelines for new market authorisations. Their comprehensive approach has inspired other regional agencies and established cooperation agreements with the European Medicines Agency to enhance information sharing and strengthen regulatory practices.

This demonstrates how connecting with international standards and agencies enables organisations to advance efficiently. Continued work through the PANDRH Network, which has operated for 25 years, should accelerate similar initiatives that ultimately improve patient access through stronger, more efficient regulatory agencies.

**How is Latin America contributing to global clinical research today, and which therapeutic areas are experiencing the most significant growth?**

Latin Americaâ??s contribution to global clinical research varies according to different studies. Regardless of the precise percentage, these figures consistently indicate that Latin America possesses the capacity for substantially greater clinical research participation.

Brazil, Mexico, and Argentina lead in volume and infrastructure development, while Chile demonstrates impressive per capita clinical trial engagement despite its smaller size. Increasing numbers of countries are recognising clinical researchâ??s strategic value across three critical dimensions.

First, clinical trials provide healthcare access for patients without alternative therapeutic options. Second, they enhance national scientific capabilities through knowledge transfer and capacity building. Third, they attract foreign investment and resources, contributing to economic development.

The fastest-growing therapeutic areas globally and regionally include oncology, rare diseases, and metabolic disordersâ??the latter encompassing diabetes and obesity, which represent significant challenges for countries like Mexico. Oncology trials in Latin America have grown 25% over the past five years, according to IQVIAâ??s 2023 analysis, indicating strong momentum in critical therapeutic areas.

Latin America offers several competitive advantages for clinical research, including genetic diversity, high patient retention rates, and strong adherence to Good Clinical Practice standards. These factors create an ideal environment for clinical trial conduct.

However, realising this potential requires enhanced regulatory harmonisation, expanded reliance mechanisms, and comprehensive capacity building initiatives. These improvements are essential for positioning Latin America as a preferred destination for global clinical research investment.

**What do you envision for the pharmaceutical industryâ??s future in Latin America, and why should the global community focus on this region?**

Latin America embodies unlimited possibilities and potential for transformative healthcare development. The region demands global attention because of its capacity for significant healthcare and economic advancement.

Our fundamental requirement extends beyond industry development to a comprehensive health sector transformation that recognises health as a strategic investment area. Health investment drives productivity enhancement and economic developmentâ??this understanding represents our greatest regional challenge and collective opportunity.

Latin America represents the land of possibilities, and our collective responsibility involves transforming potential into actionable outcomes that benefit patients and society across the region.

**As FIFARMAâ??s first female leader, what significance does womenâ??s increasing leadership representation hold for the region?**

The emergence of women in pharmaceutical leadership roles across Latin America represents encouraging progress. While I advocate strongly for womenâ??s leadership advancement, I equally champion comprehensive diversity as essential for societal evolution.

Women contribute distinctive perspectives that prove invaluable in healthcare and pharmaceutical contexts. We approach challenges differently, asking different questions that enhance dialogue quality and decision-making processes. Additionally, women often bring a deeper understanding of healthâ??s social and human dimensions.

Women traditionally serve as primary caregivers, naturally incorporating human and social considerations into every decision. This perspective ensures that patient-centred thinking remains central to all healthcare initiatives.

Increased womenâ??s participation in leadership positions helps guarantee that human dimensions are consistently integrated into healthcare decision-making, ultimately benefiting patients and communities throughout Latin America.

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