Clara Rodríguez – Executive Director, ASCIF

Our goal is simple: to ensure Colombia has access to the medicines it needs.

07.08.2025

Tags: Colombia, LatAm, ASCIF, Colombian Association of the Pharmaceutical Industry

Clara Isabel Rodríguez, Executive Director of the Colombian Association of the Pharmaceutical Industry (ASCIF), shares her journey from public sector leadership to industry advocacy. With deep experience in health regulation and public administration, Rodríguez reflects on Colombia's pharma landscape, the challenges of ongoing health reform, and why local manufacturing is vital for national and regional health sovereignty.

Could you begin by introducing yourself and sharing how you came to lead the Colombian Association of the Pharmaceutical Industry (ASCIF)?

I'm Clara Isabel Rodríguez, Executive Director of the Colombian Association of the Pharmaceutical Industry (ASCIF). The association is about to celebrate its sixth anniversary. My background is in dentistry, although I've never actually practised. Instead, I've spent my career in the public sector, holding specialisations in Health Services Administration, Social Security, and Public Law, as well as a Master's degree in Social Services from the University of Alcalá in Spain.

In terms of my professional experience, I've had the privilege of serving in several public sector roles, including Secretary of Health for the Department of Santander, and Secretary of Social Development and Secretary of Education for Bucaramanga, the capital of the department. A key experience in the pharmaceutical sector was my time as Deputy Director at the National Institute of Drug and Food Surveillance (INVIMA), where I oversaw the registration of medical devices and

the surveillance of medicines in Colombia, both before and after market launch, for four years.

That experience helped me transition into the pharmaceutical industry, where I've held various roles, particularly in advising and consulting for local, multinational, and regional companies. I also played a role in supporting Mexico's Federal Commission for the Protection against Sanitary Risks (COFEPRIS) during its certification process as a high-level regulatory agency.

Thanks to this background, a group of nine business leaders invited me to lead ASCIF nearly six years ago. We started with nine members, and now we're 32, with 25 of them being pharmaceutical plants. Colombia has a total of 98 synthetic drug manufacturing plants, and 25 of them belong to ASCIF.

There's another local industry association in Colombia, Asinfar. Could you explain the key differences between ASCIF and Asinfar, and how you complement each other within the national pharmaceutical landscape?

Asinfar is an older association, with more than 50 years of history. It originally brought together Colombia's largest domestic manufacturers and now has about 22 members, representing the most established players in the industry.

At one point, some companies that weren't part of Asinfar, or had been in the past, felt there was a gap in terms of technological development and regulatory focus compared to the larger companies. These companies felt there was a need for their representation. I always say that there are no "small" pharmaceutical companies because the investment and effort required to manufacture medicine is significant, whether it's one unit or one hundred. These companies felt underrepresented or smaller in scale, which is why ASCIF was created.

We maintain a strong, collaborative relationship with Asinfar and other Colombian trade associations, often working together on cross-sector issues.

ASCIF has always taken a highly technical approach. While we recognise the importance of political advocacy for trade associations, when it comes to a highly specialised field like pharmaceuticals, we strongly focus on regulatory and technical analysis. This is crucial because regulation directly impacts our members, the business ecosystem, and the country as a whole. Regulation sets the operating standards for our laboratories. It needs to be reviewed, questioned, and refined to ensure the right balance for compliance among local companies.

The organisation joined ALIFAR three years ago. What synergies and benefits has this alliance brought to ASCIF, its members, and to ALIFAR and the region more broadly?

We joined the Latin American Association of Pharmaceutical Industries (ALIFAR) three years ago, and it's been a valuable partnership. ALIFAR is a highly respected organisation that brings together national associations of local pharmaceutical companies from across Latin America. This is especially important because we face many common challenges in the region.

ALIFAR also participates as an observer in meetings with the PARF Network and the Pan American Health Organization (PAHO), which play a major role in shaping public health policy across Latin America. Under the leadership of Gerardo García, ALIFAR is working to build strategic alliances and frameworks for regional cooperation. We see a lot of potential in strengthening our work with ALIFAR. Although we've only been part of the network for three years, we're eager to become a much more active member moving forward.

Could you give us a general overview of Colombia's pharmaceutical industry today, covering its size, growth, and defining characteristics?

Colombia's pharmaceutical industry has traditionally focused on synthetic drug production, particularly generic and branded generics. One unique feature of the Colombian market is that not all medicines are required to demonstrate bioequivalence—only certain molecules are subject to this requirement. In addition to bioequivalent medicines, we also have high-quality medicines that, while not bioequivalent, meet rigorous standards.

All pharmaceutical plants in Colombia must first receive INVIMA certification to operate, and currently, there are 98 plants across the country. Among these, there are two significant vaccine production projects. The first is Vaxthera, a major domestic vaccine production facility underway, which is part of ASCIF and led by Dr. Jorge Osorio. A second project in Bogotá, BogotáBio, a public-private partnership with a Chinese company, SINOVAC, aimed at establishing additional vaccine production capacity.

These projects reflect a broader national vision for health sovereignty. Domestic manufacturers supply 80 percent of the medicines by volume used in Colombia's health system, and in 2024, the pharmaceutical market reached nearly COP 29 trillion. Medicines play a crucial role in healthcare delivery in Colombia.

Our healthcare model is different from many others. Under Law 100 of 1993, Colombia adopted a health insurance model through Health Promotion Companies (EPS). The Colombian Constitution defines health as a fundamental right, meaning the state is responsible for providing necessary treatments, including medicines and medical technologies. Most people don't purchase their medicines directly; instead, our industry supplies 80% of the medicines used to treat common conditions like pain, inflammation, infections, hypertension, and cardiovascular issues.

How does the split between domestically produced units and the cost of imported medicines affect the healthcare system?

It's important to highlight the value of local industry: while domestic production covers 80% of the units used in Colombia, these only account for 34% of the market's total value. This reflects the efficiency and accessibility of local manufacturing.

On the other hand, the remaining 66% of pharmaceutical spending goes toward imported medicines. These are mainly high-cost treatments for cancer, HIV, immunological conditions, and rare diseases. These are often high-value, low-volume therapies.

A major challenge today revolves around the per capita payment unit (UPC) that the government allocates to the public health insurance system, EPS. The EPS argues that the healthcare demand, or "claims ratio," exceeds the funds provided by the government. Medicines make up 28 to 30% of the total UPC budget, which must also cover hospitalisation, consultations, and surgeries.

Colombia has near-universal health coverage. Could you explain the structure of the health system and how its current challenges impact the local pharmaceutical industry?

Colombia provides healthcare to 99% of its 52 million people, and the system is divided into two main schemes. The Contributory Regime serves those with formal employment or the ability to pay, while the Subsidised Regime is designed for vulnerable groups, including many Venezuelan migrants, which has added pressure to the system.

The State plays a major role in funding the system, with resources managed by ADRES, the national fund administrator. ADRES collects funds and pre-pays UPC to the EPS, which then contracts hospitals, clinics, and medicine providers. For specialised treatments like cancer care, funding is based on maximum budgets that are estimated based on patient volumes, but this

system has been a source of controversy. The EPS argues that the allocated resources are insufficient, while the government maintains the opposite.

Recently, political tensions have risen as the government attempts to reform the health system. However, the reform has stalled in Congress, leading the government to intervene in about nine EPS, which collectively insure over 50% of the population. These interventions, which involve taking over the boards and management through the National Health Superintendency, have sparked a sector-wide crisis. This has led to significant issues, including medicine shortages, supply disruptions, delayed payments to healthcare providers, and increased out-of-pocket costs for patients who must buy unavailable medicines themselves.

At ASCIF, we don’t take political stances. Our focus is on supporting our members and strengthening the local pharmaceutical sector through dialogue and constructive proposals. While we believe the current model can be improved, the ongoing uncertainty is already causing severe consequences for both the industry and patients.

Given this context, what are the main challenges and opportunities for Colombia’s local pharmaceutical industry, and how is ASCIF addressing them?

One of the biggest challenges right now is the uncertainty surrounding the proposed health reform. Although it hasn’t been passed yet, the government is pushing for a shift towards centralised, joint procurement of medicines. Currently, EPS buy medicines through private logistics operators, who also handle the distribution. This proposed change is creating bottlenecks in funding, increasing debt across the supply chain, and limiting medicine availability in dispensaries. As a result, citizens are facing higher out-of-pocket costs, which could have long-term, irreversible consequences.

At ASCIF, we remain non-political, but we advocate for the right conditions that will help the industry thrive. The pharmaceutical sector is vital to the economy, generating around 60,000 direct jobs and at least three times that number indirectly. It represents 12% of Colombia’s industrial GDP, making it the largest manufacturing subsector in the country.

The local pharmaceutical sector contributes in two key ways: ensuring access to high-quality, affordable medicines, as evidenced by our 80% volume and 34% value contribution to the market, and driving economic growth through job creation and local investment. We’re currently working with the government on a national reindustrialisation policy. Fifty years ago, Colombia had over 230 pharmaceutical plants, but many closed after trade liberalisation in the 1990s, leaving a gap in

innovation and manufacturing capacity. We're now focused on closing that gap with a smart industrial policy.

Collaboration between the Ministry of Health, the Ministry of Trade and Industry, and INVIMA is critical to improving regulatory timelines, which is a common issue in Latin America. We maintain open and transparent dialogue with the government because our ultimate goal is simple: to ensure the country has access to the medicines it needs.

Another major area of focus is talent development. We've partnered with Colombia's 13 pharmacy schools to strengthen the local workforce. We also see an opportunity in improving our trade balance. Although we export to around 16 countries in the region, over 80% of the medicines we consume are still imported. Expanding exports of high-quality local products is something we're actively working on.

From ASCIF's perspective, what is Colombia's strategic role in strengthening the pharma sector across Latin America, and what are the opportunities for regional cooperation?

Colombia holds a strong geopolitical position in Latin America. We already export to over 70% of countries in the region and are part of key trade blocs like CEPAL, the Andean Community and the Pacific Alliance. We also have health cooperation agreements with countries such as Mexico.

Colombia can play a pivotal role in regulatory harmonisation across the region. This would allow for mutual recognition of authorisations and faster access to medicines. While countries like Brazil, Argentina, and Mexico have more established pharma sectors, Colombia stands out for its ability to support technology transfer, quality production, and affordable access. These are our core strengths.

A major challenge facing Latin America is the low production of active pharmaceutical ingredients (APIs). Most APIs are imported from China and India, which creates a dependency. While producing APIs at scale in the region is complex, there's significant potential for collaboration in developing biological and biotechnological products. This is where our R&D and investment efforts need to focus.

Colombia is eager to take the lead in this conversation, working alongside regional partners and with support from organisations like ALIFAR.

Looking ahead, what role and direction do you see for Colombia's local pharma sector in the coming years?

The Colombian pharmaceutical industry must continue to be a leader in safeguarding public health. We need to stay aligned with international quality standards to ensure that both Colombian and regional patients have access to safe, effective, and affordable medicines. Cost is a crucial factor, and no healthcare system can sustain unlimited spending without price controls.

We also need to strengthen our R&D capabilities, invest in human capital, and forge alliances with more advanced pharma nations to facilitate technology transfer. However, this is not something Colombia can achieve alone. This must be a regional effort, built on shared strengths and cooperation.

Moving forward, we must focus on innovation, embrace new technologies, and continue to ensure that our local production remains scalable and affordable. Currently, local production meets 80% of national demand, and our goal is to increase that share.

To close, what is your final message to our global readers interested in Latin America's healthcare and life sciences landscape?

My message is simple: local pharmaceutical industries are crucial for achieving health sovereignty in every country. The WHO has made it clear that the COVID-19 pandemic won't be the last, so nations need to take responsibility for securing their supply of medicines and technologies.

We must move forward as a united region by coordinating, leveraging our strengths, and creating a balanced approach. Latin America has the capability, and Colombia is ready to lead, using its knowledge and experience to help build a stronger, more self-sufficient regional health system.

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