Francisco Rossi â?? Director, INVIMA

The government is open to investors who share a long-term vision and a commitment to strengthening local capacity rather than relying solely on imports

16.10.2025

Tags:

Colombia, LatAm, INVIMA, Regulator, Regulation, Clinical Trials, Exclusive

Francisco Rossi, Director of Colombiaâ??s National Food and Drug Surveillance Institute (INVIMA), discusses the agencyâ??s ongoing transformation to become a faster, more transparent, and globally recognised regulator. Since his return in 2024, Rossi has prioritised reducing backlogs, launching the digital platform InvimÃ•gil, and refocusing INVIMA on public health surveillance. He also highlights efforts to strengthen local manufacturing, advance clinical research, and promote regional regulatory convergence through AMLAC, positioning INVIMA as a modern authority supporting both access and innovation in Latin America.

You returned to INVIMA on a permanent basis in 2024, having previously served as the agencyâ??s interim director. What was your initial assessment of the agency, and what were your first priorities?

When I arrived, there were several fronts to address. I had been at INVIMA at the start of this government in 2022 for six months, during which time we concluded that a complete restructuring and redesign of the agency was essential. After a long institutional pause, INVIMA was facing accumulated backlogs, public pressure from delayed procedures, and the loss of key technical staff.

The first priority was to reduce the overwhelming focus on commercial authorisations. INVIMA is, above all, a surveillance institution. While marketing authorisations are an important control mechanism, they had become the agencyâ??s main activity, taking excessive time and attention. Some pending procedures had been waiting between six months and six years for resolution.

This visibility around marketing authorisations, while important for investors and companies, often hides deeper risks. When procedures are delayed, the risk of corruption increases, and we needed to confront that openly. Our goal has been to make registration processes much faster, more transparent, and supported by technology â?? without compromising quality.

We are now building systems that separate technical evaluations from administrative processes, ensuring independent, evidence-based decisions. The long-term vision is an agile and trusted regulator that facilitates access to innovation while protecting public health.

INVIMA recently opened a dialogue with the pharmaceutical industry to better understand their regulatory concerns. What have you learned from these exchanges, and how will they translate into concrete improvements?

These dialogues have been essential. We started them because of the significant backlog in medicine registrations. At first, we met every two or three months; now itâ??s about every four. Through these discussions, weâ??ve improved our understanding of the challenges companies face and refined our plans for a new technological platform that will make processes faster, clearer, and more predictable.

At the same time, weâ??re shifting the agencyâ??s focus back to its true role: surveillance. When we focus too narrowly on document-based authorisations, we lose sight of whatâ??s happening in hospitals, pharmacies, and local markets. We want INVIMA to actively monitor what consumers are using, verify the quality of medicines across the supply chain, and strengthen post-market surveillance.

These roundtables have also built mutual trust. The industry now understands that the regulatorâ??s mission is not to create barriers but to ensure transparency, safety, and efficiency. Dialogue is helping both sides work toward a shared goal â?? a stronger, more competitive pharmaceutical ecosystem.

How are you ensuring that INVIMAâ??s new digital platform, InvimÃ•gil, maintains high standards of safety and quality while functioning effectively?

Thatâ??s precisely the challenge. Too often, regulatory debates become legalistic â?? about procedures rather than substance. Weâ??re determined that technical evaluations are carried out rigorously by qualified experts, in separate tracks from the procedural side.

InvimÃ•gil will introduce automated risk-based categorisation for applications, enabling low-risk products to be processed almost instantly while reserving human review for complex or high-risk dossiers. This will drastically reduce waiting times and increase traceability across the workflow.

Since 2024, INVIMA has been working to align fully with international standards. Weâ??re pursuing certification from the Pan American Health Organization (PAHO) and the World Health Organization (WHO) under the Global Benchmarking Tool (GBT), which will classify INVIMA as a globally recognised regulatory authority. Weâ??re also advancing the process to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S) so that our inspection protocols meet the same standards used by mature agencies worldwide. These efforts are part of PAHOâ??s broader digitalisation and convergence agenda in the region, and we aim for INVIMA to be one of its leading examples.

There is a strong regional push to reinforce local manufacturing and strengthen supply chain resilience. What specific steps is Colombia taking on this front?

Colombia has adopted a comprehensive industrial policy. The governmentâ??s *CONPES (Consejo Nacional de PolÃtica EconÃ³mica y Social) for Reindustrialization* includes a specific *Pharmaceutical CONPES* designed to advance pharmaceutical sovereignty. This initiative, developed by the National Planning Department and the Ministry of Health, coordinates multiple ministries and budgetary efforts to support the domestic production of essential medicines and raw materials.

In addition, the government is supporting both public and private projects through the Ministry of Science and Technology â?? particularly in vaccine production and the manufacturing of medicines deemed essential to public health. This is not only about self-sufficiency but also about strengthening resilience in future emergencies. The COVID-19 pandemic exposed how vulnerable global supply chains can be when every country depends on the same few producers.

Some flagship projects include Vaxtera, a private initiative focused on vaccines; BogotÃ¡ Bio, a publicâ??private partnership with Sinovac; Vecol, SK Bioscience, another major collaboration; and a University of Antioquia project to produce essential medicines for tuberculosis, malaria, and leishmaniasis. These projects combine public funding, academic research, and international technology transfer, all contributing to a long-term vision of regional production capacity and innovation.

Latin America is often said to have great potential in clinical research but struggles to realise it. How is Colombia progressing in this area?

Weâ??re doing quite well. Clinical research must always prioritise scientific rigour, patient safety, and ethical integrity. Itâ??s not just a form of foreign investment â?? though it does attract investment and create jobs â?? but first and foremost a scientific endeavour that contributes to public health knowledge.

Weâ??ve worked closely with the Ministry of Commerce and the Ministry of Health to align perspectives: investment is welcome, but not at the expense of ethical or scientific standards. The goal is to strengthen Colombiaâ??s research ecosystem while ensuring that clinical studies meet international benchmarks and protect participants.

Today, we have much better coordination among all actors â?? CROs, sponsors, and ministries â?? which has significantly improved the environment for research in Colombia. The number of active clinical trials has grown steadily; Colombia now ranks among the top three countries in Latin America for research activity, after Brazil and Argentina. This demonstrates both our scientific capacity and the credibility of our regulatory system.

How is INVIMA addressing new areas such as advanced therapies, cell and gene therapies, and biosimilars?

For advanced therapies, we are working hand-in-hand with research groups and developers to build appropriate regulations that reflect Colombiaâ??s context. Weâ??re analysing international models â?? from the EU, the US, and Japan â?? but critically, not copying them wholesale. CAR-T

therapies, for instance, are an area of active discussion. Weâ??re determining how best to verify quality, safety, and efficacy while encouraging local innovation and maintaining patient access.

For biologics and biosimilars, Colombiaâ??s experience is extensive. We spent nearly a decade debating how to regulate biosimilars/biogenerics and ultimately adopted a framework distinct from many other countries. While there was once a global tendency to demand extensive clinical studies for biosimilars, today there is broad recognition that such requirements were excessive and delayed competition.

Our position is clear: the distinction between â??biosimilarâ?• and â??biogenericâ?• is largely artificial. Industrial production ensures standardisation and predictability within acceptable variability ranges. Weâ??re advocating to normalise the term *biogenerics* and avoid unnecessary barriers that hinder market entry and keep prices high. This perspective aligns with recent WHO and PAHO discussions encouraging science-based, proportionate regulation.

What would you like to see more of from multinational companies in terms of communication, transparency, and collaboration with INVIMA?

This is a long-standing conversation. The global pharmaceutical industry has built a highly profitable model centred on exclusivity â?? through patents, regulation, and other mechanisms â?? that limits competition and drives prices up.

Since the mid-1990s, when medicine patents became universal, prices have skyrocketed. Itâ??s now common to see drugs that cost only a few dollars to produce being sold for hundreds of thousands because financial markets demand ever-increasing returns. This speculative model is no longer sustainable â?? even in developed countries.

Thereâ??s a growing international movement, including within the EU, calling for greater price transparency and sustainability. My view is that the pharmaceutical industry will have to adapt; otherwise, external pressures will eventually force change. Governments and regulatory agencies need to be part of this transformation, promoting models of shared responsibility and fair pricing that ensure innovation remains viable but accessible.

Colombia has been active in regional cooperation. How do you see its role in regulatory harmonisation across Latin America?

Since 2022, weâ??ve been pushing a proposal for a regional medicines regulatory agency for Latin America and the Caribbean â?? similar to what the European Union and African Union have achieved.

This is a long process requiring convergence on standards, tariffs, and border issues, but itâ??s already yielding results. Colombia, Mexico, and Cuba are collaborating closely. The new Latin American Medicines Agency (AMLAC) was launched recently, allowing us to harmonise regulatory practices and share inspections.

For example, if INVIMA and COFEPRIS (Mexico) conduct a joint inspection and agree on findings, we can mutually recognise those inspections â?? avoiding duplication and facilitating regional trade. This type of convergence benefits regulators, companies, and ultimately patients. AMLACâ??s first pilot projects are focusing on over-the-counter medicines and inspection protocols, setting the

groundwork for broader cooperation across complex therapeutic areas.

Looking ahead, how do you see Colombiaâ??s regulatory landscape evolving over the next three to five years, and what implications does this have for the region?

The trend is toward regulatory convergence rather than full harmonisation. Instead of waiting to agree on every detail, weâ??re focusing on practical collaboration â?? joint inspections, shared data, mutual recognition, and standardised processes where possible.

This pragmatic approach allows us to move faster and deliver tangible benefits for local and regional industries. As convergence deepens, Latin Americaâ??s pharmaceutical sector will become more competitive and integrated. We expect to see shorter registration times, better alignment with global standards, and more opportunities for cross-border manufacturing and research.

What message would you share with international investors considering Colombiaâ??s pharmaceutical or healthcare sectors?

Colombiaâ??s healthcare market is expanding rapidly, driven by the growth of the middle class and increasing medicine consumption. Emerging markets like ours â?? and others in Latin America and Africa â?? are where real growth lies, as mature markets in the North have stabilised.

While innovation remains largely concentrated in the North, Colombiaâ??s local industry is strong, competitive, and increasingly sophisticated. The return on investment is solid, and opportunities are multiplying, especially in generics, biotechnology, and local manufacturing.

However, multinational companies must adapt to local realities â?? particularly the purchasing power of our countries. Sustainable pricing and genuine competition will be essential for long-term success. The government is open to investors who share a long-term vision and a commitment to strengthening local capacity rather than relying solely on imports.

Finally, on a more personal note, what motivates you to serve as a public official?

Part of it is political conviction â?? the belief that government can be a vehicle for real change. But itâ??s also the awareness that when you work in the public sector, you have access to information, tools, and instruments of immense power.

Transformations within government are slow and complex because of bureaucracy, conflicting interests, and legal constraints. But when they happen, the impact is enormous. Seeing institutions evolve and citizens benefit directly from those reforms is deeply rewarding. Thatâ??s what keeps me motivated â?? knowing that, even if progress is gradual, every improvement helps make the system fairer, more transparent, and more effective.

See more interviews