RNI NO: MAHENG/2007/23118

October 16-31, 2025 |₹60

All Your Ingredients In One Magazine

Ingredients SOUTH ASIA

A Saffron Media Publication
Vol. 19, Issue 2, Pages-52

S America's real strength lies in strategic specialisation

DR SANJAY AGRAWAL

The South American pharmaceutical ingredients market is evolving from quiet dependency into a bold narrative of reinvention. For decades, the region relied heavily on imported Active Pharmaceutical Ingredients (APIs) and intermediates, but new economic realities, global supply disruptions, and health crises have shifted the focus inward.

Today, local governments, manufacturers, and multinational corporations are all aligning toward one shared goal - to strengthen domestic production, upgrade technology, and transform South America into a serious player in the global pharma ingredient ecosystem.

A Market Poised for Transformation

The pharmaceutical industry across Latin America, particularly in Brazil, Argentina, Chile, and Colombia, has been gaining momentum. Rising demand for affordable generics, chronic disease treatments, and biosimilars has created a pressing need for reliable API supply chains. What was once a market dominated by finished drug imports is now seeing increased investment in upstream activities - formulation, intermediate production, and even biologics manufacturing.

This shift is not accidental. A growing middle class, expanding healthcare access, and government-funded universal health programmes are pushing domestic pharmaceutical consumption higher each year. As healthcare systems evolve, so does the necessity for a stronger local ingredient base that can ensure affordability, quality, and uninterrupted availability.

Regulatory Evolution: Building the Framework for Growth

Regulation is no longer a barrier in South America - it's becoming a catalyst. Agencies such as Brazil's ANVISA and Argentina's ANMAT have been reforming their approval systems to align with international standards. This includes streamlining dossier submissions, harmonising pharmacopoeial requirements, and adopting digital tracking mechanisms for quality assurance.

These steps are transforming how investors perceive the region. Greater regulatory transparency reduces operational uncertainty, enabling global pharma companies to establish compliant, long-term manufacturing bases.

In Brazil, regulatory upgrades have led to an increase in local manufacturing licences, especially in therapeutic areas like oncology, cardiovascular care, and metabolic disorders. The message is clear: when the rulebook becomes predictable, investment follows.

Investment Momentum: From Import Dependence to Domestic Capacity

> Regulation is no longer a barrier in South America - it's becoming a catalyst

In the past five years, several international companies have announced new facilities or partnerships in South America - a clear signal that the tide is turning.

Brazil has been the frontrunner, attracting large-scale investments for producing APIs and sterile injectables. Argentina and Chile are also emerging as attractive hubs due to skilled workforces, strong R&D bases, and government incentives for technology transfer.

These developments are more than just factory openings. They represent a philosophical shift - from being end-market consumers to being part of the global production network.

Local companies are increasingly entering joint ventures with Asian and European partners to gain access to advanced process chemistry and compliance expertise. The result is a market that's not just growing - it's professionalising.

The Supply Chain Balancing Act

Still, the region faces a reality check: total self-sufficiency in APIs is not yet viable. South America continues to import a significant portion of its raw materials from China and India - both giants in the global ingredient trade.

However, the Covid-19 pandemic exposed the risks of overreliance on any one geography. Shipping delays, export bans, and inflated logistics costs forced governments to rethink their approach to pharma security.

The new model being adopted is one of strategic balance. South American producers are building local capabilities for critical and high-demand molecules - especially antibiotics, pain management drugs, and chronic-care APIs - while maintaining partnerships for complex or cost-sensitive inputs from Asia. This hybrid strategy offers both resilience and flexibility, ensuring supply without driving up costs beyond sustainable levels.

Country-Level Dynamics: Diversity as Strength

The regional pharma ingredients story is not uniform - each country contributes its own unique strengths to the mix.

Brazil, with its vast domestic market and evolving regulatory ecosystem, remains the anchor of South America's pharma landscape. It leads in formulation development, generics, and biosimilars production, supported by major local firms like EMS and Eurofarma.

Argentina has long had a robust scientific foundation and is now moving toward high-value biologics manufacturing and vaccine production. The government's push for local R&D partnerships is turning Buenos Aires into a biotech hub.

Chile and Colombia are focusing on stability and international collaboration. Chile's strong intellectual property framework and open trade policies attract multinationals seeking consistent operations, while Colombia's fast-growing healthcare market fuels generic drug demand.

Together, these nations form a regional mosaic of opportunity - a diversified ecosystem where strengths complement one another.

CONTINUED ON p28▶

Solvent recovery to waste minimisation

CONTINUED FROM p26

Biologics and Biosimilars: The Next Frontier

One of the most exciting trends in South America's pharma ingredients landscape is the move toward biologics and biosimilars.

As global patents on blockbuster biologic drugs expire, there's a massive opening for affordable biosimilar manufacturing. South American firms are now investing in bioprocess technology, cell culture facilities, and sterile environments necessary for large-scale biologic production.

Brazil and Argentina are leading this transformation. Both countries have launched initiatives to strengthen biopharmaceutical R&D, supported by academic partnerships and technology transfer agreements.

If these efforts continue to mature, the region could soon emerge as a credible biosimilars manufacturing hub - reducing dependency on imports while building export potential.

Sustainability and Compliance: The New Industrial Code

Today's pharmaceutical ingredient manufacturers are being evaluated not just by their capacity or price, but by how sustainably they operate.

Environmental stewardship - from solvent recovery to waste minimisation - is becoming a central expectation for companies hoping to export or partner globally.

Multinational buyers increasingly require environmental, social, and governance (ESG) compliance as part of their procurement policies.

South American producers, therefore, are modernising plants to meet green manufacturing standards. This includes adopting cleaner chemical synthesis methods, improving water usage efficiency, and investing in renewable energy sources for production lines.

Those who integrate sustainability into their operations early on will enjoy a competitive edge as global pharma supply chains continue to prioritise eco-responsibility.

Technology and Innovation: The Digital Leap

Technology is quietly reshaping the pharmaceutical ingredient industry.

Automation, AI-driven process control, and data-integrity tools are now essential for meeting regulatory expectations.

Across South America, a new generation of manufacturers is embracing digital twins, real-time analytics, and continuous manufacturing - methods that shorten production cycles and enhance consistency.

Academic partnerships are also emerging as incubators for innovation. Universities in Brazil, Argentina, and Chile are collaborating with industry players to train professionals in process chemistry, biotech, and quality systems.

This cross-pollination of research and manufacturing is the foundation for sustainable progress - creating not just factories, but future-ready ecosystems.

Policy and Public-Private Collaboration: The Roadmap Ahead

Government support remains a cornerstone of the industry's growth potential. Fiscal incentives for plant setup, streamlined customs for raw material imports, and tax benefits for R&D investments are key levers driving local production.

Public-private collaborations are expanding too. Initiatives that connect academia, industry, and policymakers are shaping the workforce of the future - one skilled not only in chemistry and engineering but also in regulatory science and sustainability practices.

Yet, progress demands patience. Building an advanced API manufacturing base requires time, trust, and capital. What matters is maintaining consistency in policy and nurturing confidence among investors that South America is not just a growth story - it's a long-term play.

Conclusion: From Importer to Innovator

The South American pharma ingredients market stands at a defining crossroads. It may never aim to rival Asia's sheer production scale, but it doesn't need to.

Its real strength lies in strategic specialisation - mastering niche segments, biosimilars, and sustainable manufacturing. By leveraging regional diversity, regulatory modernisation, and international collaboration, South America can reposition itself from an import-dependent market to a respected contributor in the global pharmaceutical supply chain.

Ultimately, this evolution isn't just about industry competitiveness. It's about healthcare sovereignty - ensuring that medicines remain accessible, affordable, and available to every citizen.

If South America continues to blend innovation with pragmatism, the story of its pharma ingredients industry will be one not of catching up - but of breaking through. ❍

(The author is scientific advisor, Alkomex GBN Pharma Group U.S.A)