



Market-shaping strategy for a sustainable vaccine manufacturing footprint in Latin America and the Caribbean

May 2026

Key takeaways

- The COVID-19 pandemic exposed critical vulnerabilities in Latin America and the Caribbean's (LAC) vaccine manufacturing ecosystem. With less than 10% of the global population, the region accounted for nearly 30% of global COVID-19 deaths. A heavy reliance on imports left the region exposed when other countries imposed export restrictions.
- Since then, the region has built meaningful momentum: new manufacturing partnerships have been created, and the share of PAHO Revolving Fund procurement regionally has grown from less than 1% in 2020 to ~23% by 2025.
- Sustaining and building on this momentum will require moving toward an expanded coordinated regional footprint capable of meeting both the region's routine immunization needs and its preparedness for future health emergencies.
- However, this analysis highlights two key structural risks to the region's vaccine manufacturing ambitions:
 - Technology transfer agreements between originators and regional manufacturers have historically been limited in geographic scope, which left regional manufacturers commercially confined to single-country supply and unable to reach the scale that regional markets could otherwise support. Several recent examples demonstrate improvements.
 - Given the strength of the PAHO Revolving Fund as a pooled procurement mechanism, demand visibility for manufacturers has become generally high, but remains restricted by large countries procuring outside the Revolving Fund and country forecasts not always translating into full procurement volumes from countries.
- Addressing these risks requires coordinated action on both fronts:
 - Technology transfer in LAC should continue to be increasingly approached as a strategic instrument to expand regional capabilities and market opportunities, with future partnerships designed for broader know-how transfer and rights to supply across multiple LAC markets.
 - The region needs a coordinated framework that connects public health priorities with manufacturing strategy, signaling to manufacturers which vaccines the region would commit to procuring from regional sources, with PAHO RF as the natural aggregation channel and country commitment as the foundation.

1. Background and Context

Latin America and the Caribbean (LAC) was among the regions hardest hit by the COVID-19 pandemic: The region represented less than 10% of the global population but accounted for ~30% of global COVID-19 deaths¹. By mid-2021, when cumulative deaths in the region had surpassed one million, only ~3% of the population had been vaccinated², making LAC one of the slowest regions to access doses at the most critical phase of the pandemic.

The international community mobilized significant resources to support vaccine access across LAC. The Pan American Health Organization (PAHO) played a central role, coordinating procurement through its Revolving Fund (RF), facilitating access to COVID-19 Vaccines Global Access (COVAX) doses, and supporting countries with surveillance, cold chain logistics, and delivery³. However, LAC had the second-lowest share of regionally manufactured vaccines globally⁴. This high level of import dependency and limited regional manufacturing scale made the region particularly vulnerable to export restrictions from other manufacturing countries.

These experiences brought regionalized vaccine manufacturing (RVM) to the forefront of the health security and sovereignty agenda in LAC. Since the pandemic, PAHO and its member states have taken deliberate steps to strengthen the region's manufacturing base. In 2021, as part of the WHO's global mRNA Technology Transfer Programme PAHO selected Bio-Manguinhos (Brazil) and Sinergium Biotech (Argentina) as regional program partners, marking an early multilateral effort to build mRNA capacity in LAC⁵. In 2024, LAC member states adopted a resolution granting the PAHO⁶ greater flexibility to incentivize local production and innovation. Since then, PAHO has facilitated regional technology transfer partnerships in the region across several antigens, including hepatitis A, varicella, influenza, and pneumococcal disease. Notable examples include a partnership between Pfizer and Sinergium for pneumococcal conjugate vaccine 20⁷ supply and, more recently, in March 2026, a partnership between CSL Seqirus and Sinergium for cell-based influenza production in Argentina⁸. Building on this collaboration, in May 2026, PAHO and CSL Seqirus announced a further agreement reserving a fixed

¹ PAHO, *PAHO and ECLAC Call for Accelerating Vaccination Processes, Transforming Health Systems and Building Welfare States to Control the Pandemic and Further the Region's Recovery*, (Oct. 14, 2021), <https://www.paho.org/en/news/14-10-2021-paho-and-eclac-call-accelerating-vaccination-processes-transforming-health-systems>.

² PAHO, *Latin America and the Caribbean Surpass 1 Million COVID Deaths - PAHO/WHO* | Pan American Health Organization, (May 21, 2021), <https://www.paho.org/en/news/21-5-2021-latin-america-and-caribbean-surpass-1-million-covid-deaths>.

³ For more on PAHO's critical role and interventions during the COVID-19 response, see: <https://www.paho.org/en/covid-19/pahos-response-region>

⁴ Javier Guzman et al., *Expanding Emergency Vaccine Manufacturing Capacity in Latin America and the Caribbean* (2022), <https://www.cgdev.org/publication/expanding-emergency-vaccine-manufacturing-capacity-latin-america-and-caribbean>.

⁵ PAHO, *PAHO Selects Centers in Argentina, Brazil to Develop COVID-19 mRNA Vaccines*, (Sept. 21, 2021), <https://www.paho.org/en/news/21-9-2021-paho-selects-centers-argentina-brazil-develop-covid-19-mrna-vaccines>.

⁶ PAHO's Directing Council, *Resolution CD61.R14 - Review of the Charge Assessed on the Procurement of Public Health Supplies for Member States*, (2024), <https://iris.paho.org/server/api/core/bitstreams/c4e40191-a5ce-4612-837c-edb3147f74ef/content>.

⁷ PAHO, *PAHO, Argentina, Pfizer, and Sinergium Drive Local Production of 20-Valent Pneumococcal Vaccine for Latin America and the Caribbean*, (Jan. 15, 2025), <https://www.paho.org/en/news/15-1-2025-paho-argentina-pfizer-and-sinergium-drive-local-production-20-valent-pneumococcal>.

⁸ PAHO, *PAHO Announces Technology Transfer Agreement in Argentina to Strengthen Regional Production of Seasonal Influenza Vaccines*, (Mar. 6, 2026), <https://www.paho.org/en/news/6-3-2026-paho-announces-technology-transfer-agreement-argentina-strengthen-regional-production>.

share of the company’s global pandemic influenza vaccine output for participating PAHO Member States, establishing an explicit regional allocation mechanism in advance of future pandemics⁹.

In parallel, the share of PAHO RF procurement value from regional manufacturers has grown from less than 1% in 2020 to ~23% by 2025¹⁰. Behind this shift sits a regional manufacturing base of 18 state-owned and private vaccine manufacturers across six countries - Argentina, Brazil, Colombia, Cuba, Mexico, and Nicaragua - at varying levels of maturity (Figure 1).

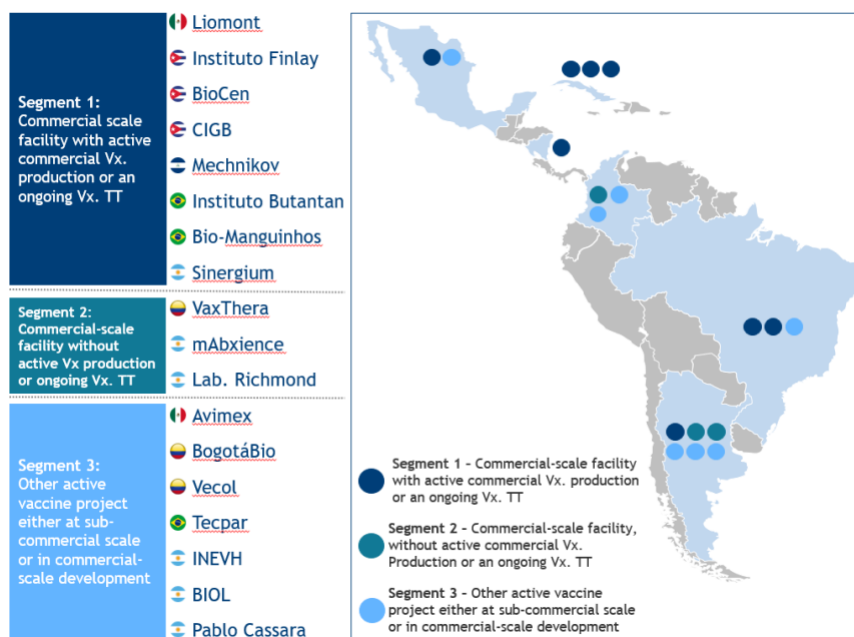


Figure 1: 18 active vaccine manufacturers in LAC segmented by commercial scale and Vx technology status

Eight manufacturers have commercial-scale facilities with active production or a technology transfer currently underway. Among them, Brazilian manufacturers Bio-Manguinhos and Instituto Butantan have built a portfolio of vaccines through a mix of self-development and technology transfer, reaching sufficient scale to supply regional markets for vaccines such as yellow fever and influenza. Cuban manufacturers Instituto Finlay and Centro de Ingeniería Genética y Biotecnología (CIGB), by contrast, have relied primarily on domestic R&D and remain focused on the national market. More recent entrants, such as Sinergium Biotech in Argentina, have typically started with drug product manufacturing, building capabilities through partnerships with originator companies.

Beyond these active manufacturers, the region's broader manufacturing base includes facilities that are built but not yet in commercial production, and a further set of earlier- or operating below commercial scale.

These manufacturers are based in a region comprising 33 countries and several territories, spanning high-income, upper-middle-income, and lower-middle-income economies. By 2035, the LAC region is

⁹ PAHO, *PAHO Signs Agreement to Reserve Pandemic Influenza Vaccine Supply for Latin America and the Caribbean*, (May 12, 2026), <https://www.paho.org/en/news/12-5-2026-paho-signs-agreement-reserve-pandemic-influenza-vaccine-supply-latin-america-and>.

¹⁰ PAHO, *PAHO's Revolving Funds Deliver 234 Million Vaccines and Critical Health Supplies in 2025, Reaching 85 Million People across the Americas*, (Feb. 19, 2026), <https://www.paho.org/en/news/19-2-2026-pahos-revolving-funds-deliver-234-million-vaccines-and-critical-health-supplies-2025>.

projected to have a population of ~700 million with a routine immunization need of ~400 million doses annually (influenza alone accounting for close to 40% of this demand)^{11,12}. As of 2025, the PAHO RF pooled ~60%¹³ of regional demand, with the remainder procured directly by countries or through other channels. As such, the LAC region is characterized by a sizeable market concentrated on specific antigens and a strong pooled procurement mechanism, which provides the region with a unique set of opportunities and challenges.

Against this backdrop, this paper commissioned by the Regionalized Vaccine Manufacturing Collaborative (RVMC) Secretariat and jointly developed with the Clinton Health Access Initiative (CHAI), aims to assess the current state of regionalized vaccine manufacturing in LAC, identify the risks and gaps that must be addressed to achieve a manufacturing footprint capable of sustaining routine immunization and responding effectively to future health emergencies, and outline the targeted interventions required to get there. This work builds on RVMC's Vision for Regionalized Vaccine Manufacturing¹⁴, which identifies the foundational priorities for achieving sustainable RVM ecosystems globally. This white paper presents the project's findings on the LAC vaccine manufacturing landscape and translates the priorities identified in the RVMC Vision into the LAC context, examining how the key pillars of a regional manufacturing ecosystem interact and what it will take for them to work together toward durable, regionally owned outcomes.

To inform this assessment, CHAI and the RVMC Secretariat conducted a structured review of the regionalized vaccine manufacturing landscape in LAC between late 2025 and early 2026, drawing on in-depth interviews and site visits with eight regional manufacturers, consultations with financiers and global partners including PAHO, the Coalition for Epidemic Preparedness Innovations (CEPI), and multilateral development banks, and secondary analysis of publicly available datasets (details in Appendix 1 and Appendix 2). The assessment examined key dimensions of the vaccine manufacturing ecosystem, including manufacturing footprint, access to products, demand and procurement, financing, and regulatory capacity, to identify the most significant gaps and risks and to propose targeted market-shaping recommendations. In this whitepaper, we prioritize the areas demanding the most attention and propose market-shaping recommendations accordingly.

2. The case for Regionalized Vaccine Manufacturing in LAC

Crafting a strategy for RVM requires first establishing why the endeavor is worth pursuing: regionalized vaccine manufacturing in LAC must be grounded in country and manufacturer decisions that address market needs, ensure the commercial viability of manufacturers, and account for routine and pandemic vaccine security.

- **Addressing market needs:** Regional manufacturers should target markets where regional production can both meet demand and reach the scale that makes operations sustainable. Since regional manufacturers may not be price-competitive initially¹⁵, markets where supply security or

¹¹ Population and demand projections based Linksbridge, *Data + Analytics: Global Vaccine Market Model (GVMM) (Access Restricted)*, <https://www.linksbridge.com/casestudy-gvmm>.

¹² Influenza demand adjusted for population growth and derived from WHO, *Influenza Vaccination Policy Database*, <https://immunizationdata.who.int/global/wiise-detail-page>.

¹³ WHO, *MI4A Public Vaccine Purchase Dataset*, (Sept. 15, 2025), <https://www.who.int/publications/m/item/2025-mi4a-public-vaccine-purchase-dataset>.

¹⁴ RVMC Secretariat, *Towards Regionalised Vaccine Manufacturing - Our Vision*, (2025), https://static.rvmc.net/downloads/2025-04/RVMC_Vision%20Document_April%202025.pdf.

¹⁵ WHO, *Global Market Landscape of Vaccine Manufacturing and Procurement*, (Dec. 16, 2025), <https://www.who.int/publications/i/item/9789240118249>.

regional relevance matter alongside price provide a practical entry point, giving time to close the cost gap without disrupting well-served markets and risking the affordability gains the PAHO RF has delivered to date.

- **Ensuring commercial viability.** LAC's projected routine immunization needs by 2035 are substantial in aggregate but unevenly distributed across antigens, with influenza accounting for close to 40% of total volume and the remaining 60% spread across smaller individual markets^{16,17}. To ensure commercial viability, manufacturers operating in the region thus need a diversified antigen portfolio and potentially other biological products (e.g., monoclonal antibodies) that can share similar manufacturing platforms¹⁸, to reach a sustainable production scale.
- **Accounting for routine and pandemic vaccine security:** Regionalized vaccine manufacturing requires a deliberate mix of platforms capable of manufacturing both routine immunization antigens, as well as antigens needed in the context of a potential pandemic¹⁹. Critically, this capacity must span the entire production process, both drug substance and drug product (Figure 2). With end-to-end vaccine manufacturing capacity in LAC, countries can increase the region's resilience against future pandemics and mitigate the vulnerabilities associated with global supply chain disruptions.

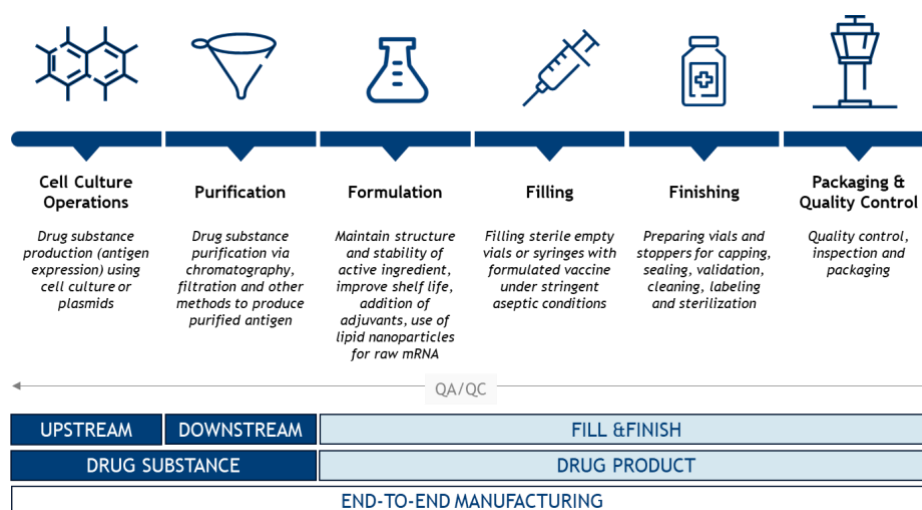


Figure 2^{20,21}: Overview of vaccine manufacturing stages: Drug Substance (DS) and Drug Product (DP), and end-to-end manufacturing

Critically for most countries in the region, domestic demand alone cannot sustain the manufacturing base needed to keep antigen platforms commercially active. Sustaining that base requires two things in parallel: manufacturers diversifying beyond national borders into multi-antigen, multi-platform

¹⁶ CEPI, *Delivering Pandemic Vaccines in 100 Days - What Will It Take?*, (2022), https://static.cepi.net/downloads/2024-02/CEPI-100-Days-Report-Digital-Version_29-11-22.pdf.

¹⁷ Influenza demand adjusted for population growth and derived from WHO, *supra* note 12.

¹⁸ Vetjaera Mekupi Haakuria et al., *Building Vaccine and Biotherapeutics Manufacturing Capacity in Africa: A Practical Approach*, 2 *DISCOV. MED.* 108 (2025).

¹⁹ Three priority technologies identified by CEPI for pandemic preparedness as offering distinct advantages for emergency response – mRNA, recombinant protein, and viral vector. CEPI, *Delivering Pandemic Vaccines in 100 Days - What Will It Take?*, (2022), https://static.cepi.net/downloads/2024-02/CEPI-100-Days-Report-Digital-Version_29-11-22.pdf

²⁰ CEPI, *supra* note 16.

²¹ Hatchett Richard et al., *Towards Vaccinating: The World Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible “Solution Space” - a Discussion Document*, (2023).

production at scale, and regional markets aligned around shared priorities and large enough to sustain those operations.

3. Market risks to achieving routine sustainability and pandemic preparedness

The long-term viability of regional manufacturers depends on several interconnected factors, from financing and regulatory alignment to access to technologies and market demand. Of these, two emerge as the most critical risks to the region's manufacturing ambitions: the limited geographic scope of technology transfer arrangements and the fragility of demand signals.

A. Limited market access

The region's vaccine manufacturing base has largely been built through technology transfer partnerships with originator companies. Across the most established manufacturers in LAC, 27 vaccines are produced at a commercial scale, most of them developed through technology transfer partnerships. An additional 16 technology transfers are in progress, reflecting sustained investment and growing technical capability.

How do manufacturers access vaccine technologies?

Manufacturers can either self-develop vaccines through their own research and development (R&D), which requires significant investment, resources, and lengthy pre-clinical and clinical trials, or acquire them through partnerships such as technology transfer, where an originator company shares the know-how to produce its vaccine with the recipient company (LAC manufacturers in this case). The originator of the technology transfer typically defines which production stages (drug product or both drug substance and drug product) are being localized and market scope.

However, the majority of these products are commercially restricted to the domestic market of manufacturers' home countries by how their technology transfer agreements have been structured. Regional exports are seen in influenza and yellow fever, where manufacturers such as Bio-Manguinhos and Butantan in Brazil and Sinergium in Argentina supply beyond their national markets. Cuban manufacturers, by contrast, remain largely focused on domestic supply. For most other antigens, the region remains dependent on imports from global suppliers.

Historically, technology originators have followed a largely consistent pattern of partnerships with manufacturers in LAC to gain access to national markets, often where local production is incentivized or required by government policy. Under most agreements, the local manufacturer gradually acquires production know-how, while the originator retains control of dose supply to the market, effectively capturing the local market for several years. In a second phase, manufacturers typically begin with drug product operations, filling and finishing the drug substance supplied by the originator, with sales often limited to a single country. An example includes Bio-Manguinhos' technology transfer from

GlaxoSmithKline (GSK) for measles-containing vaccines, where Bio-Manguinhos markets the product in Brazil²², while GSK²³ retains the right to supply the rest of the region directly.

While some technology transfer agreements in LAC include drug substance production as a longer-term objective, in practice, regional manufacturers tend to remain at the drug product stage. Progressing to drug substance requires²⁴ production volumes that domestic demand alone often cannot justify, and without access to regional markets, the commercial case for that progression is difficult to make.

Recent partnerships, such as the Pfizer-Sinergium PCV20 deal²⁵ - limited to a CMO model²⁶ - and the CSL Seqirus influenza deals²⁷, are a step in the right direction. However, more progress is needed toward regional agreements that include full end-to-end manufacturing.

Another avenue toward regional market access is the pursuit of an R&D pipeline in the region and for the region. However, to date, the broader regional R&D pipeline does not yet offer a way around this constraint.

LAC has scientific and manufacturing capabilities, reflected in vaccines developed for dengue, chikungunya, and COVID-19, with initiatives in Cuba, Brazil, and Argentina. However, beyond these examples the broader regional pipeline remains early-stage, with many candidates in pre-clinical development²⁸. Despite the important role PAHO and other regional actors play in supporting coordination and dialogue around regional production, there is still no systematic mechanism that monitors R&D progress, updates country and manufacturer priorities, and translates them into a shared list of priority products aligned with routine immunization and regional health needs. As a result, individual R&D efforts may struggle to evolve into a coherent regional pipeline that can complement, and where appropriate reduce dependence on, technology transfers from global originators.

B. Limited demand visibility

Despite the existence of PAHO RF as a strong pooled procurement mechanism pooling ~60% of regional vaccine procurement by volume (2022-2024 average)²⁹, demand predictability for manufacturers has been limited. Brazil and Mexico, the two largest markets in LAC, primarily procure vaccines outside the PAHO RF, while countries such as Argentina, Chile, and Cuba show varying levels of participation in the mechanism³⁰.

In addition, countries submit annual forecasts to the PAHO RF, and while aggregation through pooled procurement is a real strength, on its own, it is not enough to translate forecasts into firm

²² Vaccines | Portal Fiocruz, FUNDAÇÃO OSWALDO CRUZ (FIOCRUZ), <https://fiocruz.br/en/vaccines>.

²³ MMGH Consulting & Inter-American Development Bank, *Rapid Vaccine Supply Diagnostic for Latin America and Caribbean Region: Scaling up of Immunization Capacities in the PROSUR Countries*, (2022), https://web.archive.org/web/20231213131525/https://foroprosur.org/wp-content/uploads/2022/07/SALUD_Rapid_supply_diagnostic_in_LAC_Final_report.pdf.

²⁴ Progression to drug substance also depends on broader ecosystem readiness. Initial mapping efforts have begun (e.g., PAHO Mapping of Mappings workshop), but further work is needed to inform regional action.

²⁵ PAHO, *supra* note 7.

²⁶ Under a contract manufacturing (CMO) arrangement, the regional manufacturer makes the vaccine on behalf of the originator, much like a contracted producer making someone else's product to specification. The regional manufacturer cannot continue producing the vaccine independently if the contract ends.

²⁷ PAHO, *supra* note 8.

²⁸ Based on publicly available sources and focused on manufacturers that have reported vaccine-related activity. A broader view of R&D across the region, including academic institutions and early-stage initiatives, could further complement this picture.

²⁹ CHAI analysis based on WHO MI4A Public Vaccine Purchase Database WHO, *supra* note 13.

³⁰ Presented by IFC on *Workshop on Regional Vaccine Manufacturing: Mapping of Mappings in the Latin America and Caribbean Region*, <https://iris.paho.org/items/0474eb7e-131d-4e8b-9e0b-d0761ab7a44f>.

procurement signals that manufacturers can plan against. PAHO’s own monitoring illustrates the challenge: as of 2019, only 13 out of 41 participating countries and territories were able to accurately forecast at least 50% of the vaccines they procured through the PAHO RF³¹. For a manufacturer considering investing in production expansion or entry into a new antigen market, this gap between projected and actual demand makes it difficult to build a credible business case.

PAHO has continued to evolve its demand planning tools and procurement mechanisms to support regional manufacturing (Figure 3). However, these instruments can only be as effective as the commitment by countries behind them. Without broader country participation in the PAHO RF and firmer procurement commitments from Member States, manufacturers will continue to lack the demand predictability needed to justify sustained investment in expanding production.

Initiative	Year started	Scope
PAHO regional production capacity strategy - Resolution CD59.R3	2021	Urging Member States to design procurement policies that foster regional production while maintaining standards for affordability, quality, and competitiveness
PAHO Revolving Fund demand planning and forecasting	2023	Digital demand planning module for Member States to strengthen vaccine demand forecasting , match capacity to demand, and reduce underutilization risk, while providing technical cooperation to national immunization programs to improve demand planning and forecasting capacities as an input to procurement
PAHO procurement reform for regional mfct - Report CE174/27	2024	Proposals under consideration including procurement preferences for regionally manufactured products, multiyear contracts with volume commitments , regional supply agreements and stockpiles, and innovative financing mechanisms (e.g. AMC, VG) to de-risk manufacturer investments
PAHO Revolving Fund capital incentives for regional mfct - Resolution CD61.R14	2024	Allocating up to 15% of RRF capital accounts to incentivize regional manufacturing and innovation, with discretionary exemptions to the 2.5% capital fee for regionally manufactured , high-budget-impact supplies
Brazil-PAHO Revolving Fund vaccine partnership	2025	Consolidating a regional vaccine production hub through Brazil's expanded role in the PAHO RF, with BioM and Butantan producing and supplying vaccines to countries across the Americas

Figure 3: Recent PAHO RF initiatives and resolutions supporting regionalized vaccine manufacturing in LAC

Beyond predictability, a broader challenge remains in translating existing regional coordination efforts into clear, long-term demand signals for manufacturers. PAHO and other regional actors already play an important role in aligning public health priorities, procurement needs, and regional production objectives. However, these efforts are not yet systematically connected into a framework that links priority-setting, manufacturing strategy, and credible procurement commitments. As a result, manufacturers continue to face uncertainty about whether future demand will materialize at the scale and duration needed to justify regional production.

³¹ PAHO’s Directing Council, Final Report CD59/INF/7 - Plan of Action on Immunization, (2021), <https://www.paho.org/sites/default/files/2021-08/CD59-INF-7-e-immunization.pdf>.

A combined risk: technology access and demand signals

These two dynamics are mutually reinforcing. Commercial arrangements restricted to domestic markets prevent manufacturers from reaching the scale needed to compete and sustain operations, while weak demand signals undermine the case for regional technology investment. The absence of regional coordination across these two areas risks limiting the collective impact of efforts. Without deliberate alignment between demand, disease burden, and access to technologies, the region may continue to build manufacturing infrastructure that is politically significant but economically fragile.

C. A maturing but heterogeneous enabling ecosystem

While the region’s regulatory landscape offers a relatively solid foundation with most manufacturers based in countries recognized as PAHO Functional National Regulatory Agencies (NRA) for Vaccines (i.e., Argentina, Brazil, Mexico, and Cuba), enabling access to PAHO’s RF and easing regulatory pathways^{32,33}, manufacturers across the region face concerns over approval timelines and limited access to early scientific advice during vaccine development including in more mature regulatory environments like Mexico and less mature like Colombia. Regulatory harmonization and flexibilization initiatives are underway through PAHO and the Community of Latin American and Caribbean States (CELAC) and will be particularly important in emergency contexts, where faster cross-country alignment can reduce delays.

While manufacturers did not indicate financing as an immediate constraint - most regional manufacturers report access to sufficient capital to sustain ongoing operations - investment decisions remain shaped by weak demand visibility, the absence of reliable offtake arrangements, and declining political prioritization of pandemic preparedness. These constraints are further compounded by macroeconomic volatility, including currency fluctuations and tariffs on imported inputs, which manufacturers identify as constraining investment decisions while continuing to erode margins and undermine long-term planning.

Operational constraints related to workforce availability and access to critical inputs, such as single-use systems and spare parts, pose further challenges for manufacturers. With heavy reliance on imported consumables, manufacturers are exposed to delays, high costs, and vulnerability to global supply disruptions. While this study did not assess these factors in depth, they represent important dimensions of the regional manufacturing ecosystem that warrant further examination.

4. Proposed market-shaping strategies to address market risks

The risks identified in this analysis will require coordinated action across multiple stakeholder groups. While several initiatives are already underway, and progress since the COVID-19 pandemic has been meaningful, significant gaps remain. The interventions outlined below are designed to bridge these

³² PAHO, *Quality Assurance of Health Technologies*, (Feb. 13, 2026), <https://www.paho.org/en/topics/quality-assurance-health-technologies>.

³³ Looking forward, the ongoing transition from the PAHO NRA framework toward integration with the WHO Listed Authorities (WLA) framework will introduce adaptation challenges over the coming years and warrants attention as part of the region’s broader regulatory strategy

gaps, building on existing momentum while addressing the structural barriers that continue to limit the region's manufacturing potential.

A. Expanding access to technologies with a regional scope

Technology transfers in LAC should be approached as a strategic instrument to expand regional capabilities and market opportunities for regional manufacturers. This will require a shift in the negotiation of technology transfer arrangements, their financing, and the capabilities needed to absorb and build on transferred technologies.

Restructuring how partnerships are negotiated. Future technology access agreements must be structured for regional marketing authorization and, where feasible, include drug substance rights – enabling manufacturers to access the volumes needed to sustain operations and progress toward the production independence that both commercial viability and pandemic preparedness demand. Achieving this requires a more deliberate approach to how technology partnerships are brokered. Rather than leaving deal structures to bilateral negotiations between individual manufacturers and originators, regional actors can help create a more enabling environment for technology transfer. PAHO, through its regional cooperation and procurement functions, with support from the RVMC Secretariat, through technical advice and market-shaping analysis, can support manufacturers and countries in identifying priority antigens and platforms for regional production and exploring how pooled procurement or other regional instruments could strengthen manufacturers' business case. Underpinning all of this are credible country demand signals: without a clear indication of priority needs and procurement intentions from the demand side, even well-structured technology partnerships risk being built on uncertain foundations.

There are early models to build on. The March 2026 agreement between CSL Seqirus and Sinergium for cell-based influenza³⁴, facilitated by PAHO, leverages pooled procurement to de-risk a technology transfer with regional reach and secure a competitive price for the region. Furthermore, the WHO mRNA Technology Transfer Programme with Bio-Manguinhos and Sinergium as LAC participants offers a different model focused on building platform capacity³⁵.

Reorienting financing. Over the past five years, manufacturers in the region have raised significant funding, predominantly from development finance institutions and governments, but most investment has been directed at domestic-focused projects, with limited conditions for regional commercial scope or drug substance rights. While this has supported important infrastructure development, it has left a gap: future investment must prioritize regionally scalable, end-to-end manufacturing over domestic-only projects to ensure sustainability.

Strengthening LAC's capacity to develop vaccines for routine and emergency scenarios. The region's early-stage development pipeline leaves it heavily dependent on external technology transfers. The WHO mRNA technology transfer program in Brazil and Argentina³⁶ and CEPI's investments in platform technologies are building important foundations³⁷, but the technology base remains narrow. Extending that momentum to other pandemic-priority platforms, including recombinant protein and viral vector, would broaden the region's capacity to respond to a wider range of health threats. Governments are well-positioned to lead this effort, investing in vaccine R&D as a regional public good and creating the conditions for sustained innovation across platforms.

³⁴ PAHO, *supra* note 8.

³⁵ PAHO, *supra* note 5.

³⁶ *Id.*

³⁷ For CEPI's specific investments in the LAC region, see: <https://cepi.net/our-portfolio>

B. Expanding access to technologies with regional scope

As this study has described, demand signals for regional manufacturers remain suboptimal and fragmented, limiting their ability to plan, invest, and compete. Action is required on three fronts: Strengthening country procurement through the PAHO RF, creating demand for regionally manufactured vaccines, and adopting a shared framework aligning regional health priorities with manufacturing strategy.

Strengthening country procurement through PAHO RF. PAHO RF is the region's strongest mechanism for aggregating demand across countries, but its effectiveness depends on governments doing three things: consistently procuring through it, submitting realistic forecasts, and securing multi-year budget commitments where possible. Regional bodies such as Southern Common Market (MERCOSUR) and CELAC can reinforce these efforts by championing regional sourcing as a health security priority and building political momentum to sustain country commitments over time.

Creating demand for regionally manufactured vaccines. Countries should adopt locality of manufacturing and capability for manufacturing for the region as a criteria in vaccine product selection—alongside price, programmatic fit and supply considerations—to strengthen the value placed on supply security and regional preparedness. This would create a meaningful demand signal within existing procurement channels without requiring new institutional infrastructure or compromising the affordability gains that pooled procurement has delivered. A practical step is ensuring that regionally produced vaccines appear on the RF's product list alongside global alternatives.

Adopting a shared framework. The LAC region would benefit from a coordinated framework that links future public health priorities with manufacturing strategy, signaling which vaccines the region would consider procuring from regional sources. PAHO and the RVMC Secretariat, drawing on their analytical work and convening role, are well positioned to lead this effort, with governments providing the demand commitments that give it credibility. Such framework would benefit of having a periodic process that identifies priority vaccines and signals future product priorities based on criteria such as health impact, value-for-money and equity. A model along these lines, adopted to the LAC region's demand and financing context, could signal future health priorities and enable manufacturers to plan pipelines. While carrying some inherent risk, manufacturers' R&D decisions would be taken against a clearer picture of regional need. And the regional industry could minimize the likelihood of duplicative capacity building.

C. Strengthening the enabling ecosystem

Realizing the recommendations above will depend on parallel progress on the broader ecosystem conditions that shape how the region's manufacturing base operates. Expanding regional scope must be matched by regulatory strengthening in countries where manufacturers face delays and limited support, alongside efforts to expand the list of recognized regulators in the region. This requires continued progress on regulatory reliance and harmonization of technical requirements, so that a single regulatory dossier can serve multiple markets.

Several enabling elements fell outside the scope of this study but warrant further examination. These include the availability of skilled workforce and access to inputs and consumables, as well as the role of universities, research institutions, and vaccine development platforms in building longer-term regional innovation and product development capacity. Moreover, strengthening RVM in LAC is as much a question of industrial policy, trade, and cross-sector coordination as it is a health sector challenge, and future work should examine the governance architecture needed to align incentives across

ministries of health, industry, trade, and finance. Structured assessment of each of these dimensions would meaningfully strengthen the evidence base and inform the design of targeted interventions.

4. Conclusions and Recommendations

Over the decades, LAC has built a meaningful vaccine manufacturing base across countries, platforms and antigens, supported by the unique regional asset of the PAHO RF. As this study has shown, most of that capacity remains confined to domestic markets, sustained by technology transfer arrangements that limit what manufacturers can produce and for whom. Furthermore, while the PAHO RF effectively aggregates regional demand for procurement, signaling long-term demand that manufacturers can plan against remains a challenge. With post-pandemic political attention gradually shifting and global health financing under pressure, the conditions that have supported recent progress cannot be taken for granted.

Addressing these constraints requires action from all parts of the ecosystem:

- **Governments**, in the near term, should support clear regional demand signals by submitting realistic forecasts to the PAHO RF and translating them into firmer procurement commitments. Investment in technology transfers should be linked to regional supply rights and, where feasible, progression beyond drug product. Regional manufacturing should be a meaningful criterion in vaccine product selection, with weight given to supply security. Over the medium to long term, sustained progress will depend on continued investment in reliance pathways and convergence of technical requirements, and on arrangements that give all participating countries concrete benefits such as priority supply access during emergencies.
- **Regional actors** should align with PAHO's important advances regarding demand-side instruments, technology transfers, and regulatory initiatives. In the near-term, PAHO and partners should continue to operationalize the demand-side instruments already under discussion (e.g., multi-year contracts, volume guarantees, advance market commitments) and rally member states and partner support behind these mechanisms. Sustained facilitation of technology transfer partnerships that include drug substance scope and provide manufacturers with regional demand signals should remain a priority. Over the medium-term, maintain coordination on regulatory reliance and harmonization across LAC national regulatory authorities will be essential to enabling regional market access. The longer-term objective should be a coherent centrally coordinated, regional framework linking LAC's health priorities to its manufacturing strategy, drawing on the diverse manufacturing capabilities of the region, ensuring the region builds what it needs.
- **Financiers and donors** must align capital with regional objectives, conditioning investment on regional commercial scope and drug substance production rather than reinforcing domestic, drug product only models. R&D across priority vaccine platforms should be treated as a regional public good, with funding structures that reflect shared benefit rather than individual country returns. In the near term, this means applying regional scope as a baseline criterion in investment decisions; over the medium term, it means developing financing instruments, including insurance mechanisms and blended finance structures, that distribute the cost of preparedness more equitably across the region.
- **Manufacturers** must push for regional scope in technology partnerships, demonstrate quality and supply reliability, and pursue South-South co-development as a pathway to reducing dependence on originator-defined terms.
- **Supporting partners**, including the RVMC Secretariat, CEPI, and technical advisors, have a role in convening stakeholders, sharing cross-regional learning, and providing analytical and advocacy

support that helps coordinated regional action come together. Throughout, these partners should position their contributions in support of, and complementary to, PAHO's established regional coordinating role – reinforcing the principle of subsidiarity that underpins and effective regional health architecture.

Strong data infrastructure underpins effective market-shaping. Credible demand forecasting, procurement visibility, shared market intelligence, and transparent information of supply and platform capacity are foundational inputs to every intervention proposed in this paper. Without them, regional strategies risk being built on incomplete information, and manufacturers, financiers, and policymakers alike lack the visibility needed to act with confidence.

Many of the actions outlined in this paper are already underway across the region. What this study brings together is a consolidated view of where the most critical gaps remain and where coordinated effort can have the greatest impact. Closing them will require sustained effort across the actors named above, alongside further work on other areas, such as supply chain factors, that fell outside this study's scope. We urge stakeholders across the ecosystem to take these findings forward and advance the actions needed to build a regional manufacturing ecosystem that strengthens pandemic preparedness, supports healthy vaccine markets, and is commercially sustainable over the long term.

About Us

About RVMC

The Regionalized Vaccine Manufacturing Collaborative (RVMC) is a global initiative advancing vaccine equity and health security by enabling sustainable regionalized vaccine manufacturing ecosystems. Founded in 2022 by the Coalition for Epidemic Preparedness Innovations, the National Academy of Medicine, and the World Economic Forum, RVMC focuses on strengthening manufacturing and supply chain networks across three priority regions - Africa, Latin America and the Caribbean, and Southeast Asia.

Hosted and funded by CEPI, the RVMC Secretariat operates through a collaborative, partner-led model, working across sectors to advocate for change, align stakeholders to accelerate progress, advise on sustainable approaches, and account for progress. Through this approach, RVMC strengthens regional manufacturing ecosystems and helps enable more equitable and resilient access to vaccines worldwide.

For more information, please visit: www.rvmc.net

About CHAI

The Clinton Health Access Initiative, Inc. (CHAI), is a global health organization committed to saving lives and reducing the burden of disease in low-and middle-income countries. CHAI works to strengthen the capabilities of both governments and the private sector in those countries to create and sustain high-quality health systems that can succeed without ongoing assistance.

CHAI's approach is unique. Our aim is not just to impact a problem, but to fundamentally change the way in which the problem is addressed to solve the issue. We use a business-minded methodology to shape healthcare markets to reduce the costs of lifesaving medications and other critical health care products. We work in partnership with governments to reform their health systems, targeting areas where current methods are failing.

For more information, please visit: www.clintonhealthaccess.org

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Appendices

Appendix 1: Scope of the study

This assessment, commissioned by the RVMC Secretariat and jointly conducted with CHAI, in its entirety, is structured around five critical success factors for RVMs:

- **Manufacturing footprint:** Does the region have sufficient manufacturing infrastructure and installed capacity to produce vaccines at a scale meaningful for both routine immunization and pandemic response?
- **Access to Products:** Do RVMs have access to the necessary technologies, and product portfolios to meet market demand across LAC?
- **Regulatory environment:** Are regulatory pathways sufficiently robust, harmonized, and efficient to enable timely market access for RVMs across LAC countries?
- **Demand & Procurement landscape:** Is demand sufficiently predictable and are procurement mechanisms structured in a way that creates viable, scaled market opportunities for RVMs?
- **Access to Financing:** Do RVMs have adequate access to the financing instruments needed to sustain investment in capacity expansion, R&D, and long-term operations?

While all five dimensions were assessed, the analysis revealed the most significant gaps and market risks concentrated in two areas, namely, **Access to Products and Demand & Procurement landscape**. Accordingly, this paper directs its market shaping recommendations toward these two factors, which also closely align with the RVMC Secretariat's strategic vision and priorities for 2030.

For those interested in a deeper exploration of the remaining dimensions, i.e., Regulatory Approval, Manufacturing Footprint and Access to Financing, please reach out directly to the RVMC Secretariat at ariane.abreu@rvmc.net or CHAI at vtoure@clintonhealthaccess.org

Appendix 2: Data Sources

To ensure the analysis is grounded in both data and practical realities, the study draws on a combination of primary and secondary research:

- Secondary sources include reliable databases such as the Linksbridge GVMM demand forecast, the WHO MI4A database, Global Burden of Disease studies, as well as existing literature on RVM in LAC, including regional work developed by several organizations discussed during the PAHO Workshop on regional vaccine manufacturing: Mapping of mappings in the Latin America and Caribbean region and PAHO official documents & working documents.
- Direct engagements were conducted with seven manufacturers from Mexico, Cuba, Colombia, Brazil, and Argentina to capture the supply landscape, including installed capacity, R&D initiatives, and technology transfer partnerships, as well as manufacturer perspectives on demand-side challenges and enabling factors such as regulation and financing.
- Findings were further validated through consultations with regional and global financiers to assess their appetite for investment in LAC vaccine manufacturing, and with partners including PAHO and CEPI, both of whom are actively advancing important work in this space.

Appendix 3: Glossary

Abbreviations and acronyms:

Abbreviation	Expansion
CELAC	Community of Latin American and Caribbean States
CEPI	Coalition for Epidemic Preparedness Innovations
CHAI	Clinton Health Access Initiative
CIGB	Centro de Ingeniería Genética y Biotecnología
CMO	Contract Manufacturing Organization
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus Disease 2019
DP	Drug Product
DS	Drug Substance
GAVI	Global Alliance for Vaccines and Immunization
GSK	GlaxoSmithKline
GVMM	Global Vaccine Market Model (Linksbridge)
LAC	Latin America and the Caribbean
MERCOSUR	Southern Common Market
MI4A	Market Information for Access to Vaccines (WHO database)
mRNA	Messenger Ribonucleic Acid
NRA	National Regulatory Agencies
PAHO	Pan American Health Organization
PCV20	20-valent Pneumococcal Conjugate Vaccine
R&D	Research and Development
RF	Revolving Fund (PAHO)
RVM	Regionalized Vaccine Manufacturing
RVMC	Regionalized Vaccine Manufacturing Collaborative
UNICEF	United Nations Children's Fund
VIS	Vaccine Investment Strategy
WHO	World Health Organization

Key terms:

Term	Definition
Drug Substance (DS)	The production of the active ingredient used in a vaccine. For example, growing a virus in cell cultures or synthesizing an mRNA sequence.
Drug Product (DP)	Commonly known as fill-and-finish, involves formulating that ingredient into the final vaccine and packaging it into vials or syringes.
End-to-end manufacturing	Refers to performing both Drug Substance (DS) and Drug Product (DP) steps.
Ever-warm capacity	Manufacturing infrastructure, workforce, and biological platform capabilities kept continuously active and operationally ready, so that production can be scaled up rapidly when needed.
Fill-and-finish	The final stages of vaccine manufacturing, in which formulated drug substance is filled into primary containers, inspected, sealed, labelled, and packaged for distribution.
Originator	The company that holds the original intellectual property and know-how for a vaccine and that licenses or transfers that technology to other manufacturers through technology transfer agreements.
PAHO Revolving Fund	A pooled procurement mechanism operated by PAHO, through which participating Member States consolidate their vaccine demand to access high-quality vaccines at lower prices and with greater supply security than they could achieve individually.
Regulatory harmonization	The alignment of regulatory standards, requirements, and procedures across multiple countries to facilitate cross-border market access for health technologies.
Regulatory reliance	An arrangement through which a National Regulatory Agencies accepts or gives significant weight to the assessments and decisions of a trusted reference agency, reducing duplicative review and accelerating time to market.
Routine immunization	The regularly scheduled program of vaccinations delivered to children and other priority populations as part of national immunization schedules.
Technology transfer	The process by which an originator transfers vaccine production technology, know-how, and processes to another manufacturer to enable local or regional production.
Vaccine platform	The underlying technology used to develop and produce vaccines (e.g., mRNA, viral vector, protein subunit, inactivated, live-attenuated).