

Expanding Emergency Vaccine Manufacturing Capacity in Latin America and the Caribbean

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INTRODUCTION

The COVID-19 pandemic has transformed the global vaccine manufacturing landscape, with capacity more than doubling in the past 18 months. Before the pandemic, manufacturers produced an estimated total of five billion vaccine doses each year.¹ In 2021, manufacturers produced 12 billion doses of COVID-19 vaccine, with 1.4 billion doses produced in December alone.² The push to rapidly scale vaccine manufacturing has also expanded manufacturing beyond the traditional set of firms and countries. Many middle-income countries—including China, India, and Brazil—have grown and cemented their position as key vaccine suppliers or have become key global and regional suppliers. The Latin America and Caribbean (LAC) region relies heavily on imported COVID-19 vaccines (see Table 1), having the second lowest level of domestic supply after Africa. The pandemic has also spurred the invention of new technologies, such as mRNA vaccines, which have proven remarkably successful in preventing severe symptoms, hospitalization, and death. The rollout of the COVID-19 vaccine has also been faster and more equitable than any vaccine campaign in history, despite important lags in vaccination coverage rates in the lowest income countries. The number of annual COVID-19 vaccinations

Table 1. Sources of COVID-19 vaccine supply in LAC, as of December 31, 2021

Arrangement type	Number of doses (million)	Share (%)
Contracted supply via COVAX	46.6	5.8
Direct donations	34.4	4.3
Domestic supply	124.6	15.4
Donations via COVAX	9.9	1.2
Supply via AVAT	0.1	0
Supply via bilateral deals	591.8	73.3
Total	807.4	

Source: WTO-IMF COVID-19 Vaccine Trade Tracker. Accessed February 22, 2022. Available here: https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.htm

1 Airfinity, COVID-19 Vaccine Production Report Prepared for Vaccine Supply and Production Summit. March 8, 2021. Available here: https://www.ifpma.org/wp-content/uploads/2021/03/Airfinity_global_summit_master_final.pdf

2 Airfinity, COVID-19 Intel Report Prepared for the IFPMA, BIO, and DCVMN Press Briefing. December 15, 2021.

delivered during the pandemic is already 8.9 times the size of the global flu vaccination program and 21 times that of annual measles vaccinations.³

However, despite these relative successes, the COVID-19 pandemic has highlighted the extent to which the current model of vaccine manufacturing and distribution is highly concentrated geographically, making supply vulnerable to nationalism, export bans, and shortages. For example, India's export ban cut off critical supply to COVAX, which had invested most of its initial funds in the Serum Institute of India. As a result, coverage rates lagged in low- and middle-income countries that depended on COVAX for vaccines, including several countries in LAC. Shortages of inputs like syringes also stifled global access to emergency vaccines. This supply constraint coupled with minimal pre-existing arrangements and slow responses to coordinate and invest in vaccine development by most middle-income governments with sufficient ability to pay left nonpharmaceutical interventions as the only defense against the virus in the first several waves of the pandemic in most countries in LAC.

The pandemic has also shown that current manufacturing and regulatory arrangements are not as responsive and adaptable as they need to be to quickly mitigate outbreaks and prevent and respond to global pandemics. Importantly, the COVID-19 pandemic was not a once-in-a-century calamity; estimates suggest that pandemic risks are high, with the chance of a pandemic on the scale of COVID-19 hovering around 2.5–3.3 percent each year.⁴ Just as governments devise emergency response strategies for natural disasters with large death tolls like earthquakes and hurricanes and allocate significant funds to prepare for those events, they must also invest proactively and significantly in increased manufacturing capacity for emergency vaccines in response to pandemic threats.

In response to this new reality and the limitations evidenced by the pandemic, many countries and regions are now interested in making significant investments to introduce and/or ramp up manufacturing of emergency vaccines with the aim of stockpiling or developing “ever-warm manufacturing capacities” ready to scale up when pandemic-potential pathogens strike. In the LAC region, several countries, including Argentina, Brazil, Chile, and Colombia, have pledged to accelerate manufacturing capabilities, and regional platforms such as the Forum for the Progress and Development of South America (PROSUR)⁵ and the Pan American Health Organization (PAHO) have launched regional initiatives to boost vaccine production and ensure the region is ready to respond swiftly to the next pandemic threat.

High-level political interest and funding to increase regional manufacturing capacity in LAC is needed. At the same time, regional and national policymakers must balance multiple, sometimes competing policy goals and address unintended consequences, identifying trade-offs and potential mitigation strategies (See Figure 1). For example, bolstering manufacturing capacity at the national or regional level can improve the resilience of supply chains and protect them from collapse when an emergency hits, but focusing on self-sufficiency can delay efforts to develop and deploy vaccines at a time when the speed of response is crucial. Strengthening local manufacturing capabilities can also come at the cost of efficiency, affordability, and equity. And within each of these goals, there are multiple design and financial requirements that require further thought and development around the world. For

3 Glassman A, Kenny C, Yang G. COVID-19 Vaccine Development and Rollout in Historical Perspective. Center for Global Development Working Paper 607. February 2022. Available here: <https://www.cgdev.org/publication/covid-19-vaccine-development-and-rollout-historical-perspective>

4 Metabiota. “What Next? Predicting the Frequency and Scale of Future Pandemics.” CGD virtual event. July 20, 2021. Recording available here: <https://www.cgdev.org/event/whats-next-predicting-frequency-and-scale-future-pandemics>

5 PROSUR members include Argentina, Brazil, Colombia, Chile, Ecuador, Guyana, Paraguay, and Peru. Surinam and Uruguay have “guest country” status.

Figure 1. Different policy goals associated with increasing vaccine manufacturing capacity in LAC



example, how much must be done domestically versus regionally versus globally? Many are inspired by the US government’s Biomedical and Advanced Research Development Authority, which facilitated unusually focused and efficient contracting through Operation Warp Speed, stimulating innovation through guaranteed demand and financing.⁶ Operation Warp Speed also conducted supply chain mapping to identify vulnerabilities and proactively target investments in vaccine manufacturing capacity. However, this model requires many elements currently missing from government and public expenditure management in middle-income countries.

Expanding manufacturing capacity is a critical component of comprehensive preparedness policy, but it alone is not sufficient to ensure rapid and effective responses to future pandemic risks. Policymakers must therefore work to increase manufacturing for emergency vaccines alongside complementary efforts to improve pandemic preparedness and response, such as by developing adequate surveillance systems to prevent and detect emerging infectious diseases, updating national preparedness plans, building resilient national systems with appropriate and relevant skills and funding to adequately respond to future health crises, and contributing to international agreements that address the financing and governance of global and regional pandemic preparedness plans and response.

This note outlines first-order demand and supply considerations that policymakers in the LAC region must understand and put in place to increase the likelihood of successful, fit-for-purpose manufacturing initiatives that can lead to rapid and equitable access to emergency vaccines now and into the future.

KEY ELEMENTS FOR SUCCESS ON THE DEMAND SIDE

To scale up manufacturing effectively in the event of a pandemic risk, decision makers must consider the volume and timeline of demand for emergency vaccines as well as the mechanisms available to procure these products. Key demand-side considerations to ensure stable access to emergency vaccines in LAC in future health emergencies include:

⁶ Adler D. “Inside Operation Warp Speed: A New Model for Industrial Policy.” Vol. V, n.2, *American Affairs*; 2021. p. 3–32.

- 1. Assuring fiscal space to spend on routine vaccine procurement as well as ever-warm and surge vaccine manufacturing and purchasing.** Fiscal challenges related to the pandemic threaten the level of investment in developing manufacturing now and procuring vaccine in the event of a pandemic threat. The LAC region suffered a staggering 6.8 percent contraction in gross domestic product in 2020⁷ and pandemic-related fiscal challenges associated with slow to moderate growth will likely persist over the medium term, especially as variants like Omicron continue to stall economic recovery. In addition to the pandemic response, governments face competing, costly priorities within and outside of the health budget. PROSUR governments, for example, spend about \$2.3 billion on routine immunization each year and must sustain—and possibly expand—this investment to achieve sufficient vaccination coverage as well as to create strong incentives for manufacturing.⁸ Governments must also mitigate the uncertainty introduced by the current pandemic as well as future risks to enable adequate investment. Historically, governments have estimated demand for emergency health products including vaccines on a year-by-year basis—the governing principle of the PAHO Revolving Fund. However, the COVID-19 pandemic has shown that the trajectory of a pandemic is difficult to predict from one month to the next, let alone on an annual basis. Governments must adapt amidst the budget constraints and uncertainty introduced by a pandemic threat to ensure sufficient, sustainable financing is available for vaccine purchasing.
- 2. Projecting future vaccine demand.** Adding COVID-19 and seasonal influenza vaccines to countries' Expanded Program on Immunization portfolios could help ensure a certain quantity of stable demand going forward, enabling larger volumes on a regular basis and thereby making scale-up in the event of a risk more viable. The volume of anticipated demand—and therefore the extent of the impact on cost and availability—will also depend on the type of vaccine, both in terms of pathogen and technology platform and whether demand is estimated at the national, regional, or global level. Stable demand projections for other products that can be manufactured at the newly developed sites, such as monoclonal antibodies, is also necessary as this approach can help build an ecosystem for sustainable, flexible manufacturing, thereby ensuring access to emergency vaccines when needed. Although the volume and timing of vaccine demand is difficult to calculate for an unknown future pandemic threat, reasonable estimates can be made for key threats, including influenza, Zika virus, Chikungunya, Dengue, Rift Valley Fever, and Lassa Fever. The region can also leverage the work conducted by the World Health Organization on the Research & Development Blueprint for Action to Prevent Epidemics to identify potential threats and understand potential manufacturing demands.
- 3. Assessing relation to existing procurement arrangements, such as the PAHO Revolving Fund.** Increasing subsidies to domestic or regional vaccine manufacturing may lead more countries to “buy local,” potentially increasing the costs of vaccination on average and decreasing the volumes of pooled purchasing via the PAHO Revolving Fund. It would have a big effect on the Fund if its largest client countries exit. PROSUR countries together account for about 75 percent of the total value procured.⁹ Any country in the LAC region interested in expanding its manufacturing

7 Economic Commission for Latin America and the Caribbean. Growth in Latin America and the Caribbean in 2021 Will Not Manage to Reverse the Adverse Effects of the Pandemic. July 8, 2021. Available from: <https://www.cepal.org/en/pressreleases/growth-latin-america-and-caribbean-2021-will-not-manage-reverse-adverse-effects>

8 World Health Organization and UNICEF Joint Report Form. Government expenditure on routine immunization (US\$). Accessed January 5, 2022. Available here: <https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/planning-and-financing/immunization-financing-indicators>

9 Pan American Health Organization. Unedited Annex to the Financial Report of the Director. September 3, 2020. Available here: <https://www.paho.org/en/documents/cd58-od360-annex-e-financial-report-2019>

capacity but also willing to preserve this important regional asset must therefore consider how its potential supply-side investments for vaccine manufacturing fit within the policies and financing model of the PAHO Revolving Fund. Additional analysis on why country governments may decide to opt out of cooperative purchasing mechanisms like the PAHO Revolving Fund and buy bilaterally would also be essential to enable the development of better mechanisms and incentives for securing a stable demand in the future.

- 4. Signing long-term contracts and revenue guarantees for routine procurement.** Buying locally or regionally produced vaccines may create incentives for firms, contribute to the security and resilience of the supply chain, and increase the level of competition in the market, especially given that markets recently enlarged. However, it can also increase the price of vaccines, which may be sold more cheaply elsewhere. Governments need to consider their commitment to paying a premium for local and regional production, including the size of the price increase and how long such a premium can be sustained. Contracts for routine procurement should also continue to be channeled through the PAHO Revolving Fund, as it is a uniquely functional procurement mechanism for middle-income countries that should be reinforced. Other regions, like Africa, are exploring pooled procurement arrangements to improve access to quality and lower-cost vaccines, ensure the sustainability and resilience of the supply chain for medical products, and achieve economic and political gains, looking to the PAHO Revolving Fund in the Americas as a leading example.
- 5. Signing at-risk contracts (or advance market commitments) for pandemic-related vaccine manufacturing and procurement.** At-risk contracts would allow governments to signal their commitment to enable the level of vaccine manufacturing needed to respond when a health emergency emerges. Promising future demand through these at-risk contracts enables firms to raise financing to build facilities and maintain workforces to make sure emergency vaccines are available when needed.

KEY ELEMENTS FOR SUCCESS ON THE SUPPLY SIDE

Significant resources are required to scale up manufacturing, and decision makers must target their investments strategically to achieve efficiency and maximize value for money. Key supply-side considerations to support a rapid and effective increase in manufacturing capacity for emergency vaccines in LAC include:

- 1. Capital investment.** Building manufacturing facilities and maintaining a trained workforce and surge capacity for manufacturing emergency vaccines require significant resources. Estimates from the G20 High Level Independent Panel (HLIP) on Financing the Global Commons for Pandemic Preparedness and Response suggest that \$60 billion would be needed up-front to fully expand global production to respond to future pandemic threats.¹⁰ Estimates also suggest that each individual mRNA facility with the capacity to produce 100 million doses would cost from \$127 million to \$270 million.¹¹ In addition to subsidies from the public sector, private sector money from future demand contracts and profit earned from competitive markets are key sources for financing. The HLIP recommends 30 percent co-funding by the private sector. Any initiative in

¹⁰ G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response. A Global Deal for Our Pandemic Age. July 2021. Available from: <https://pandemic-financing.org/report/foreword/>

¹¹ Médecins Sans Frontières. Share mRNA Technologies, Save Lives. August 2021. Available from: https://msfaccess.org/sites/default/files/2021-09/COVID19_TechnicalBrief_MSf_mRNA_vaccines_ENG_20.9.2021_0.pdf

the region should also be able to leverage global funding and to work with key global brokers like the Coalition for Epidemic Preparedness Innovations and the multilateral development banks.

2. **Private sector engagement.** Financing from the private sector will be crucial to increase manufacturing capacity given the scale of resources needed. Also, multinational firms would have to grant access to intellectual property (IP) and facilitate technology transfer to enable manufacturing to take place in new locations by new producers. New local and regional manufacturers could potentially sidestep intellectual property rights issues, such as how the Afrigen Biologics and Vaccines company in South Africa worked with the World Health Organization to make its own version of Moderna's mRNA vaccine against COVID-19 independent of Moderna.¹² Although mRNA COVID vaccines could be developed based on publicly available sequences, without the involvement of the IP owners, it costs more and takes longer, especially since the new manufacturing sites would have to scale up to commercial scale manufacturing level, source critical input materials, document and validate the new manufacturing process, and conduct clinical trials to demonstrate safety, efficacy and quality.
3. **Integration with the global system and market.** Manufacturers must define their intended market and make the adequate upstream arrangements, including securing critical input materials for the manufacturing process, as needed. Additionally, manufacturers would need to secure adequate financing to scale to the desirable production output. For example, the amount of investment needed to establish an mRNA facility that will supply a strictly regional market will differ significantly from the amount needed for a facility that intends to sell around the world.
4. **High-impact products and manufacturing phases.** Decision makers must make strategic choices about the products and manufacturing phases to prioritize, with the understanding that only manufacturing of active substances and finished products will secure better access arrangements and swift responses to pandemic threats in the future. Decision makers should coordinate investments and consider a diverse range of manufacturing technologies to secure diverse production capacity and should also prioritize highly flexible manufacturing technologies that can quickly pivot to modify vaccines to target variants and/or be repurposed to produce routine vaccines in non-pandemic times.¹³ During the COVID-19 pandemic, mRNA technology has proven more adaptable and cost-effective than cell-based vaccine technologies, as it is easy to reformulate against new variants. Evidence also suggests mRNA vaccines can be used effectively against other diseases,¹⁴ which would create new markets for the existing technology. Investing in mRNA vaccines—or similarly promising, flexible, and accessible future technologies—represents a smart, sustainable investment. In addition to vaccines, countries should also consider if there is value in manufacturing critical input materials either right at the start, or as a follow-on step from manufacturing vaccine active substances.
5. **Location.** Decision makers must consider key criteria such as existing manufacturing capabilities, regulatory capacity, the trained workforce, and the size of the market when determining where to invest. The LAC region has six national regulatory authorities of regional reference (Argentina, Brazil, Colombia, Cuba, Chile, and Mexico) and is home to two of the seven

12 Maxmen A. South African scientists copy Moderna's COVID vaccine. *Nature*. February 3, 2022. Available from: <https://www.nature.com/articles/d41586-022-00293-2>

13 Yadav P, Désir A. "Boosting Vaccine Production Needs the Right Degree of Flexibility." *INSEAD*. November 2021. Available here: <https://knowledge.insead.edu/operations/boosting-vaccine-production-needs-the-right-degree-of-flexibility-17621>

14 Kumar A, Blum J, Le TT, Havelange N, Magini D, Yoon IK. "The mRNA vaccine development landscape for infectious diseases." *Nature*. February 2022. Available here: <https://www.nature.com/articles/d41573-022-00035-z>

non-high-income countries currently producing WHO-prequalified vaccines (Brazil and Cuba). Fourteen manufacturers in five countries (Argentina, Brazil, Chile, Cuba, and Mexico) are involved in the production of COVID-19 vaccines, but they mainly function as contract manufacturing organizations responsible for completing the fill and finish process.¹⁵ No mRNA manufacturing is currently taking place in the region, even though PAHO announced the creation of two regional hubs for the development and production of mRNA-based vaccines in Argentina and Brazil in September 2021. Strategic investments based on sound criteria will ensure that manufacturing capacity is increased efficiently in a sustainable manner.

CONCLUSION

Scaling manufacturing for emergency vaccines effectively and sustainably in LAC depends on decision makers' abilities to clarify and agree on the many possible policy goals, acceptable trade-offs between these goals, and potential mitigation strategies to increase the likelihood of better outcomes for the population, government purchases, and the market. The structural and financial arrangements for producing and buying emergency vaccines must be strategic, as they will be difficult to change once established and will shape LAC's trajectory in this pandemic and in future health emergencies. Further research and learning will inform key recommendations for expanded manufacturing capacity in LAC, which will ensure the region is well-positioned to respond swiftly and effectively to health emergencies and remain competitive with the rest of the world.

¹⁵ Interamerican Development Bank and MM Global Health Consulting. "Public-Private Forum: Opportunities and synergies for the production of vaccines in South America." PROSUR virtual event. January 20, 2022. Recording available here: <https://youtu.be/Su4tEN3dw1Q>



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