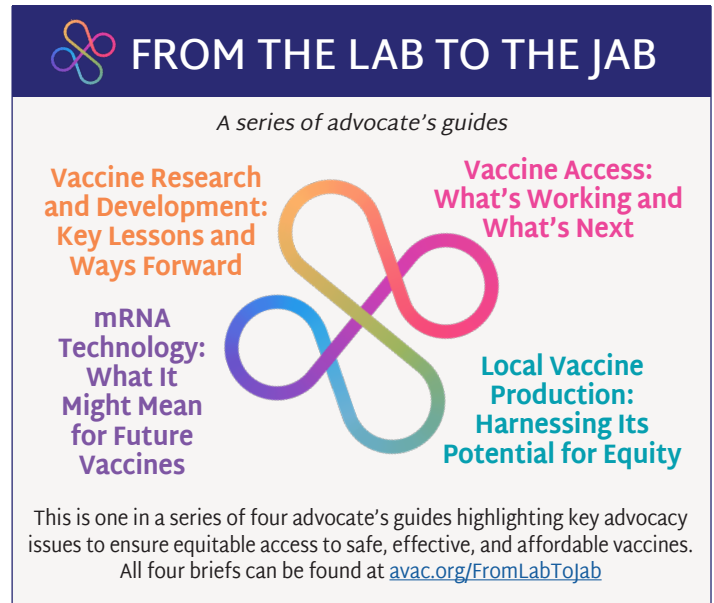


Local Vaccine Production: Harnessing Its Potential for Equity

Ensuring equitable access to safe, effective and affordable vaccines involves advocacy across multiple areas. This issue brief on local vaccine production covers the current state of local production, what is needed to facilitate it, and ideas for advocacy to harness its potential. It is one of four briefs in a series providing a roadmap for advocacy to advance the development of essential vaccines for HIV, COVID-19, TB and other global public health threats, including approaches to ensure equitable access to these life-saving vaccines once developed. Additional topics cover the research and development (R & D) process, issues around global access; and the advent of the mRNA platform for vaccines.



Key Points

- Local production of vaccines in low- and middle-income countries (LMIC) is an important part of the solution to global vaccine inequity and supply shortages.
- Local production is especially important for Africa, since it produces less than 1% of the vaccines it administers.
- Enabling local production will require substantial and sustainable government investment, innovative financial instruments, access to intellectual property (IP), technical capacity, strong supply chains, and 10 to 20 years.

Vaccine Access and Equity

Inequitable access to vaccines has been a persistent, deadly problem in low- and middle-income countries (LMIC), which was worsened by COVID-19 vaccine nationalism and high-income country (HIC) hoarding. Although governments co-funded development of COVID-19 vaccines, pharmaceutical corporations have controlled their production, pricing and access, putting profit over global public good.

Most LMIC do not produce their own vaccines, leaving them vulnerable to supply shortages and high pricing. Globally, less than ten vaccine producers have extensive portfolios, the capacity for global reach, and a variety of deployable technologies.¹ Overall, 90% of all global vaccine revenue goes to four HIC-based companies – GSK, Pfizer, Merck (MSD), and Sanofi. The European Union (EU) produces the world's largest volume of vaccines, followed by India, China and the United States.

India is the main vaccine supplier for LMIC.² Access to vaccines in LMIC is funded mainly through donors, such as UNICEF, Gavi, and, during the COVID-19 pandemic, COVAX. Gavi supplies to countries

with a gross national income of less than \$1,730 per capita (participating countries must contribute at least 35% of the financing). Middle- and upper-middle-income countries purchase vaccines from pharmaceutical companies, sometimes at even higher prices than HIC pay. For example, Oxfam reported that Moderna charged South Africa \$30-\$42 per dose for its COVID-19 vaccine, versus \$18 per dose in the EU, and the New York Times reported that Botswana, Colombia and Thailand were paying \$27-\$30 per dose.^{3,4,5} Astra-Zeneca and Johnson & Johnson (J&J) have also charged more for their COVID-19 vaccines in LMIC than in HIC, while Pfizer/BioNTech have not been transparent about COVID-19 vaccine pricing in LMIC.⁶

Local production – ideally of vaccines produced and controlled by local companies, researchers and governments – is an important part of the solution to global vaccine inequity, but other access and regulatory barriers also need to be addressed for global health equity.

Depending on profit-driven monopolies – or a single source – to supply COVID-19 vaccines has had disastrous global and national repercussions. J&J, Moderna and Pfizer/BioNTech were unable to meet demand for COVID-19 vaccines, which delayed deliveries as the pandemic was raging. South Africa's production contract with J & J required the country to waive its right to restrict exports of COVID-19 vaccines. In 2021, J&J exported millions of vaccines from South Africa, where they had been bottled and packaged, to the EU - instead of fulfilling South Africa's desperately needed order of 31 million doses.⁷ Using a single source – Serum Institute of India (SII), which promised to make a billion doses of the Oxford/AstraZeneca COVID-19 vaccine for LMIC, as COVAX's main supplier – backfired. In early 2021, India's intense wave of the Delta variant led its government to impose a ban on exporting vaccines, including 190 million doses for intended for COVAX.

Local production is especially important for Africa, since the continent manufacturers less than 1% of the vaccines it administers. Currently, vaccine production facilities are established in Egypt, Ethiopia, Morocco, Senegal, South Africa, and Tunisia. However, these operations have limited capacity, primarily completing end-stage operations of vaccine production (known as fill-and-finish, which involves final packaging of vaccines produced elsewhere into small single or multiple use vials and labeling).

Without local vaccine production, especially manufacturing products from start to finish, African countries are vulnerable to health emergencies, outbreaks of preventable diseases, unaffordable vaccines, inadequate or delayed supply, and shortages. Countries without local vaccine production and related R&D capacity may lack the vaccines that are necessary for addressing their specific public health needs.

Time to Expand on Existing Models of Local Production Outside HIC

The Developing Countries Vaccine Manufacturers Network (DCVM) is an alliance of over 40 vaccine producers from 15 LMIC; it offers trainings, helps its members to acquire funding, and supplies vaccines to 170 countries.

LMIC vaccine manufacturers have overcome supply, production, and regulatory challenges, especially during the COVID-19 pandemic, including in Brazil, China, Cuba, India, Indonesia, Iran, Kazakhstan, Pakistan, Russia, Thailand, and Vietnam.

Public-sector vaccine production allows countries to address public health needs, direct manufacturing, and distribution priorities, and streamline regulatory coordination to accelerate the addition of newly proven vaccines into national guidelines and healthcare systems. Enabling local researchers to contribute to the development of vaccines that address local health needs and are adapted to health system contexts is critical for establishing greater resilience and self-sufficiency. As examples, Brazil's investment in vaccine research, development and manufacturing enabled it to fulfill 54% of domestic

needs and to export vaccines to the region. Public-sector production in Cuba made it possible to cover 72% of domestic need – and achieve universal vaccination.⁸ Indonesia supported public-sector vaccine production with legislation requiring use of locally sourced materials, local ownership of production facilities, and a local workforce.

In some LMIC, private-sector local manufacturers (such as India’s SII and Argentina’s Synergium) also supply the public health system through deals with ministries of health.

Enabling Local Production

Whether through the public sector or agreements between ministries of health and private companies, local production requires substantial, sustainable investment from governments, innovative finance instruments, and other stakeholders to create an end-to-end economic model that delivers for public health. It also requires access to intellectual property (IP), technical capacity, strong supply chains, and time.

Getting a vaccine manufacturing facility running can take up to three years. Building costs range from \$50 million to \$700 million.⁹ There are additional costs for maintenance, raw materials, training and labor, and compliance with Good Manufacturing Practices (GMP, the international standards for vaccine production and quality control). GMP compliance is required by most national regulatory authorities (NRA) and for World Health Organization (WHO) prequalification, which enables procurement by United Nations agencies, Gavi, and the Global Fund.

Achieving economies of scale requires time to grow domestic and regional markets. Locally-produced vaccines will initially cost more to manufacture and will be more expensive than imported vaccines. But local production has value that goes far beyond lower pricing and achieving economies of scale – it is essential for global health equity.

What Governments, Donors and Civil Society Can Do

Governments and donors need to invest in local R&D and manufacturing capacity, fund advance purchase agreements and be willing to pay higher prices for locally-produced vaccines; donors need to commit to procuring locally-produced vaccines, and civil society must play a leading role in setting priorities for vaccine research and access, from trial design to policy agendas.

Actions for local producers include:

- Partnering with governments and civil society to prioritize vaccine R&D and production, build demand, and ensure inclusion in national guidelines and health systems.
- Sharing market intelligence with other manufacturers across the continent, to create a coordinated, sustainable market for locally-produced vaccines, including for export.
- Addressing IP barriers. See our vaccine access brief as part of this series at, <https://avac.org/FromLabToJob/>.
- Finding partners for technology transfer – the “know how” to produce a vaccine – which can be a lengthy and expensive process.
- Committing to staff training to develop future capacity for an expanded scope of vaccine production.
- Developing a stable, robust vaccine manufacturing process, since the biological raw materials (microorganisms and human, animal or plant cells) used to produce vaccines – excluding mRNA-based vaccines – can be unstable and unpredictable.
- Avoiding supply shortages, ideally by sourcing raw materials locally.

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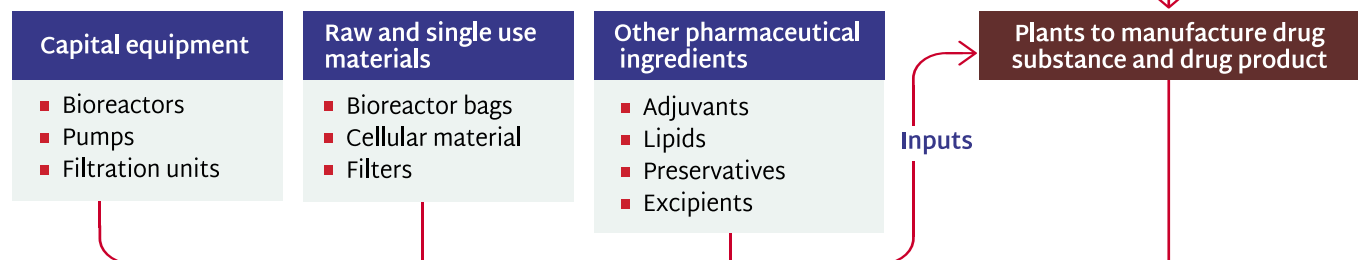
- Developing expertise related on submitting product dossiers to NRA for marketing authorization. This can be complicated, confusing, and lengthy. Many NRA operate with constrained resources, and their processes may not be harmonized.
 - The African Medicines Regulatory Harmonization Program, the African Vaccine Regulatory Forum, and the African Medicines Agency are working to improve the continent’s regulatory processes. For more information, see: <https://nepad.org/>, <https://www.afro.who.int/health-topics/immunization/avaref>, and <https://www.nepad.org/microsite/african-medicines-agency-ama>.
 - Vaccines authorized by WHO-certified NRA are eligible for WHO prequalification. WHO prequalification, which can be a lengthy process.. The WHO offers technical assistance for compliance with international standards and dossier preparation. For more information, see: <https://www.who.int/news-room/articles-detail/specialized-technical-assistance-medicines>.

Vaccine Manufacturing is a Multi-Stage Process that Often Requires Extensive Collaboration

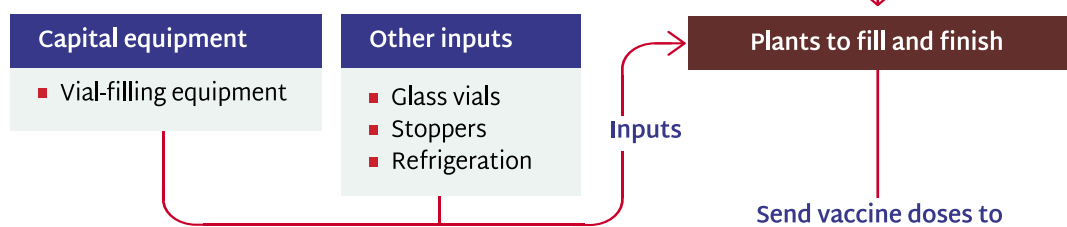
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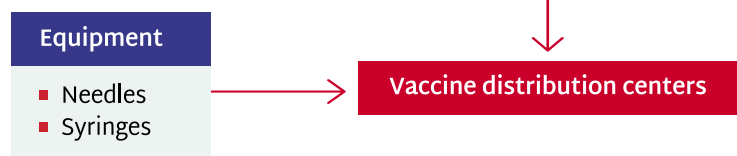
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Distribution



Source: Chad P. Brown and Thomas J. Bollyky. Forthcoming. “How COVID-19 vaccine supply chains emerged in the midst of a global pandemic.” PIIE Working Paper.

Targets and Initiatives for Local Vaccine Production in Africa

The ecosystem for expediting the pathway from vaccine development to local manufacturing must be supported and sustained.

■ **The WHO mRNA Vaccine Technology Transfer Hub**

The mRNA vaccine technology transfer hub was established in 2021 and is supported by WHO, the Medicines Patent Pool and the ACT-Accelerator/COVAX; its hub is in South Africa. This initiative aims to increase LMIC capacity for mRNA vaccine production (for COVID-19 and other applications). It has established a center of excellence and training, for sites in several LMICs, including Argentina, Indonesia, Brazil, Kenya, Nigeria, and Senegal (which is home to MADIBA, Africa's first high-volume vaccine production facility).

The hub relies on non-exclusive licenses. The Moderna vaccine was selected after the company pledged not to enforce its COVID-19-related patents in 92 LMIC.¹⁰ Although Moderna has not shared the know-how needed to manufacture the vaccine, researchers at Afrigen Biologics and Vaccines in Cape Town, South Africa, were able to deconstruct and rebuild the vaccine on their own (a process called reverse engineering).

To be successful, this initiative must have leadership from the global South, with support from the global North. For more background, check out the recent AVAC and CASPR- supported webinar [What's All the Buzz About: mRNA, Manufacturing, Vaccine Access](#).

■ **Five-Year Strategy of the President's Emergency Plan for AIDS Relief (PEPFAR)¹¹**

The United States partnership to accelerate regional manufacturing includes initiatives to increase local production of medical products in Africa. PEPFAR's five-year strategy also prioritizes regional manufacturing and sets targets for procurement and deployment of locally-produced HIV diagnostics and antiretroviral medicines. By 2025, PEPFAR plans to procure 15 million tests produced by African manufacturers; by 2030, PEPFAR and its partners aim to shift at least two million patients on first-line ARV treatments to African-made products.

■ **Manufacturing in Africa for Disease Immunization and Building Autonomy (MADIBA)**

The Development Finance Corporation will provide financing for private-sector projects that build regional vaccine manufacturing capacity, such as MADIBA in Senegal, Africa's first high-volume vaccine production facility.

■ **The Partnerships for African Vaccine Manufacturing Framework for Action (PAVMFFA)**

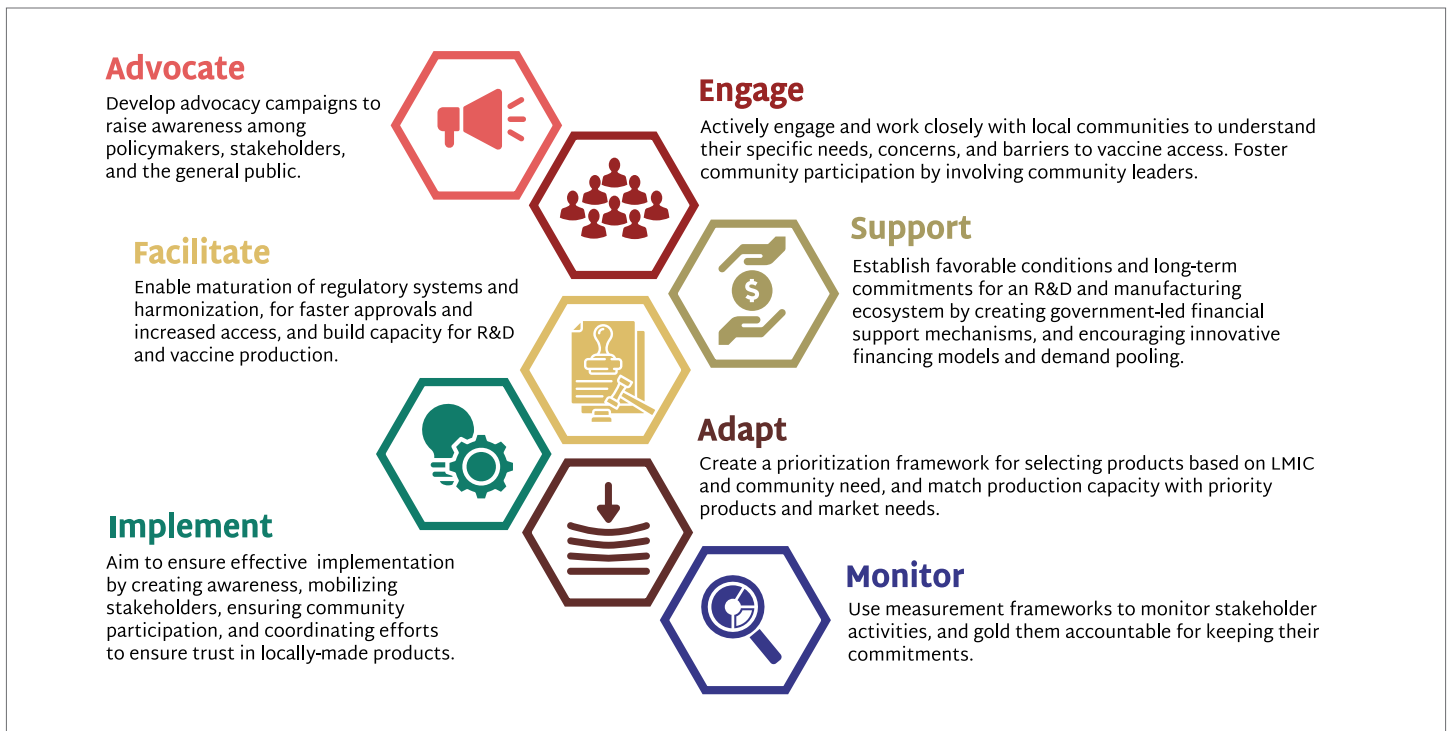
The PAVMFFA and the Africa Centers for Disease Control have created a framework for local vaccine production, and have set targets for African industry to produce 10% of the continent's doses by 2025, 30% by 2025, and 60% percent by 2040.

■ **The Clinton Health Access Initiative (CHAI)**

CHAI has created a database of local vaccine manufacturing commitments and technology [transfers](#).

■ **The Wellcome Trust**

The Wellcome Trust works towards developing a reformed ecosystem for R&D, and for scale-up of geographically diverse and [sustainable](#) manufacturing capability.



What Can Advocates Do?

Civil society must be able to meaningfully participate in vaccine research prioritization, and implementation initiatives, as well as new initiatives to increase local manufacturing. Advocates can:

JOIN OR INITIATE CAMPAIGNS to raise awareness of the need for local vaccine production and generate support for investment.

PROMOTE technology transfer and development of IP-free vaccines.

ADVOCATE to governments, donors and UN agencies for advance purchase commitments and procurement of locally-produced vaccines, and for lower-interest, longer-term loans to enable local vaccine production.

SPEAK OUT about global health inequity, including the need for local vaccine production.

COLLABORATE with national health authorities and local producers to ensure that all WHO-recommended vaccines are adopted into national guidelines, and to prioritize vaccines that meet national public health and community needs, such as health threats that are neglected by HIC vaccine makers.

CONSULT with communities, healthcare workers, health system managers and other key stakeholders on what's needed to scale up vaccine roll-out.

JOIN forces to advocate for policies and resources to improve vaccine roll-out, such as initiatives to train and pay community health workers to administer vaccines off-site.

BUILD DEMAND for locally-produced vaccines, through on-the-ground education that reaches communities who are left behind by top-down initiatives; address vaccine hesitancy and dispel misinformation.

SUPPORT the mRNA vaccine technology transfer hub and other initiatives to enable local production.

Resources

- AFRICAN VACCINE MANUFACTURING INITIATIVE: <https://www.avmi-africa.org/>
- DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK: <https://dcvmn.org/who-we-are-what-we-do/>
- GLOBAL VACCINE MARKET REPORT 2022: https://cdn.who.int/media/docs/default-source/immunization/vaccine_access_market/global-vaccine-market-report-2022-template-final2.pdf
- PARTNERSHIPS FOR AFRICAN VACCINE MANUFACTURING (PAVM) FRAMEWORK FOR ACTION: <https://africacdc.org/download/partnerships-for-african-vaccine-manufacturing-pavm-framework-for-action/>
- PEPFAR FIVE YEAR STRATEGY: <https://www.state.gov/pepfar-five-year-strategy-2022/>
- PLOTKIN S, et al. THE COMPLEXITY AND COST OF VACCINE MANUFACTURING – AN OVERVIEW: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/>
- SCALING UP AFRICAN VACCINE MANUFACTURING CAPACITY: https://cms.wellcome.org/sites/default/files/2023-01/Wellcome-Biovac-BCG-Scaling-up-African-vaccine-manufacturing-capacity-report-2023_0.pdf
- Gavi: [Expanding sustainable vaccine manufacturing in Africa: Priorities for Support](#)
- New York Times: [Can Africa Get Close to Vaccine Independence? Here's What It Will Take, April 25, 2023](#)

Footnotes

¹ <https://www.who.int/publications/i/item/9789240062726>

² <https://www.bruegel.org/blog-post/world-divided-global-vaccine-trade-and-production>

³ <https://www.oxfam.org/fr/node/17295>

⁴ <https://www.bmj.com/content/372/bmj.n281>

⁵ <https://www.nytimes.com/2021/10/09/business/moderna-covid-vaccine.html>

⁶ <https://www.pharmaceutical-technology.com/features/covid-19-vaccine-pricing-varies-country-company/>

⁷ <https://www.nytimes.com/2021/08/16/business/johnson-johnson-vaccine-africa-exported-europe.html>

⁸ <https://tdtmvjournal.biomedcentral.com/articles/10.1186/s40794-021-00135-5>

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518734/>

¹⁰ <https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx>

¹¹ https://www.state.gov/wp-content/uploads/2022/11/PEPFARs-5-Year-Strategy_WAD2022_FINAL_COMPLIANT_3.0.pdf

About This Brief

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About AVAC

AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Twitter [@HIVpxresearch](#); find more at www.avac.org, www.prepwatch.org and www.stiwatch.org.