Expanding the capacity to produce vaccines in Africa
Enablers and Barriers
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Expanding the capacity to produce vaccines in Africa: Enablers and Barriers

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Abbreviations

ACT Access to COVID-19 Tools
AIDS Acquired immune deficiency syndrome
AMA African Medicines Agency
AVAT African Vaccine Acquisition Trust
DPT Diptheria-perstussis-tetanus
EPI Expanded Programme on Immunisation
GMP Good manufacturing practices
HIV Human immunodeficiency virus
HPV Human papilloma virus
ICH International Council for Harmonisation
IFC International Finance Corporation
IP Institut Pasteur
LMICs Low- and middle-income countries
ML Maturity level
MMR Measles, mumps, rubella
mRNA Messenger ribonucleic acid
NCL National Control Laboratory
NRA National Regulatory Authority
R&D Research & development
SOP Standard operating procedure
UNICEF United Nations Children’s Fund
USP United States Pharmacopeial Convention
WHO World Health Organization
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Foreword

Globally, immunization programs are a significant and effective method for combatting more than 20 infectious diseases, preventing close to 5 million deaths per year from illnesses like diphtheria, pertussis, and tetanus (DPT), and measles. Immunization programs are also important control measures for emerging diseases, such as Marburg virus, Lassa fever, Ebola, and COVID-19.35

By the end of 2021, nearly all countries had introduced COVID-19 vaccines. However, by January 2022, only 10 percent of the African population had been fully vaccinated against SARS-CoV-2.1 Disappointingly, in the subsequent six months, 35 countries in Africa remained at 10 to 40 percent vaccine coverage.2

Across Africa, 99 percent of vaccines are imported, and many countries are reliant on donations or donor-driven initiatives to provide vaccines.3 Following the multiyear delay in receiving an adequate supply of COVID-19 vaccines, stakeholders on the continent, led by the African Centres for Disease Control and Prevention, set out a bold plan to manufacture 60 percent of the continent’s vaccines in Africa by 2040.

The U.S. Pharmacopoeial Convention (USP) has been working for decades to help expand pharmaceutical manufacturing capacity in low- and middle-income countries (LMICs), strengthen regulatory and laboratory systems, and develop workforce expertise through training and knowledge transfer.4 These principles can translate to a greater certainty for a consistent and sustainable supply of quality vaccines for countries in Africa. USP is partnering with donor organizations to accelerate LMIC access to quality COVID-19 medicines, including vaccines.5,6

In this white paper, we discuss some of the barriers and enablers to expanding vaccine manufacturing in Africa. Local manufacturing can help reduce dependence on donor programs and create resilient vaccine supply chains, resulting in improved public health systems and reduced morbidity and mortality. Lessons learned from previous efforts to successfully expand the global pharmaceutical manufacturing sector can inform the growth of vaccines manufacturing on the African continent, not only for COVID-19 vaccines, but also for routinely used vaccines and those that address African-specific diseases. Expanding the continent’s vaccine manufacturing industry can also spur economic growth and prosperity, leading to supplies of vaccines for in-country use as well as exporting vaccines to neighboring countries and regions.
The Current Ecosystem of Vaccine Manufacturing in Africa

Africa’s manufacturing industry contributes to fewer than one percent of the vaccines used on the continent. Current capacity produces fewer than 100 million vaccine doses and is not currently equipped to achieve larger scale production.¹ The vaccines produced are used for national supply, in the countries where they are made, with very little export to neighboring countries or other regions. Numerous initiatives, spurred in part by the COVID-19 pandemic, are diligently working to change and expand the manufacturing landscape.

To date, eight countries (Algeria, Egypt, Ethiopia, Morocco, Nigeria, Senegal, South Africa, and Tunisia) have vaccine manufacturing capacity within nine companies operating across the vaccine value chain. Only Senegal is producing and exporting a yellow fever vaccine, which has achieved World Health Organization (WHO) prequalification. Nine countries are acquiring or plan to acquire new or additional vaccine manufacture capacity. Existing vaccine production facilities are primarily focused on fill and finish, labeling and/or packaging operations, or vaccine importation. Five companies are developing fully integrated manufacture capabilities that include drug substance generation and purification, as well as complex drug product manufacturing operations, including fill and finish.² There is limited interest in vaccine research and development (R&D) of novel vaccines.

In the absence of locally produced and affordable vaccines, Africa relies on importing products, and most countries receive support for routine vaccine procurement through Gavi, the Vaccine Alliance. Gavi is a public-private partnership and multilateral funding mechanism created in 2000 to assist countries in expanding routine immunization coverage.

A Snapshot of Africa’s Growing Vaccine Capacity

This vaccine manufacturer landscape shows five countries with end-to-end manufacturing capabilities (orange); three countries currently able to label, pack, or import vaccines (purple); and additional countries acquiring production capabilities.³ ⁴

DS = drug substance, DP = drug product, EPHI = Ethiopian Public Health Institute, F&F = fill and finish, IP = Institut Pasteur, KBI = Kenya BioVax Institute
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Gavi has partnered with 40 African countries to ensure access to vaccines, averting close to 9 million vaccine-preventable deaths and supporting more than 1 billion vaccinations through campaigns.¹ Once available, locally produced vaccines may help complement these traditionally used procurement sources and help assure a consistent and resilient supply of vaccines. This is particularly important as countries in Africa become eligible to graduate from Gavi based on gross national income per capita.

The Case for Local Manufacturing of Vaccines in Africa: Why It Matters

Africa’s reliance on imported vaccines, combined with the continent’s lack of organized negotiating and purchasing power, has resulted in unacceptable delays in securing access to COVID-19 vaccines. In early 2022, the African continent had received only about 6 percent (540 million) doses out of the 9 billion COVID-19 vaccine doses produced, despite having 17 percent of the world’s population.¹⁰ By the third quarter of 2022, the number of COVID-19 vaccines delivered to the continent had risen to just under 1 billion doses, still insufficient to meet Africa’s public health needs.¹¹ This inequity remains, despite the efforts of COVID-19 Vaccines Global Access (COVAX), the vaccine pillar of Access to COVID-19 Tools (ACT) Accelerator, and the African Vaccine Acquisition Trust (AVAT) to provide COVID-19 vaccines for the African population.¹²

Recognizing the existing inequity and vulnerability that exists due to the need to import vaccines and acknowledging that the continent’s demand for all vaccines will continue to grow, African countries and stakeholders set ambitious goals for the vaccine sector. The African Union has a stated objective of reducing vaccine imports from 99 percent to 40 percent by 2040.¹³ Similarly, the framework of the Partnership for African Vaccine Manufacturers aims to enable 30 percent of vaccines procured to be produced by African manufacturers by 2030.¹⁴ Without the expansion of additional local sourcing options for vaccines, Africa may likely suffer similar delays in access during future global health pandemics.

From a health security standpoint, delays in vaccine access also impact disease control efforts by allowing existing or new variants to become established and spread, which can threaten the health and well-being of people in Africa, as well as people across the world. Delays in immunization affect financial burden as well, with recent studies estimating that Africa will bear the greatest economic setbacks from the COVID-19 pandemic.¹⁵

Apart from the recent need for equitable access to vaccines to combat COVID-19, a more resilient supply is necessary to minimize interruptions and shortages of routine childhood vaccines against polio, DPT, and measles, among others. The vaccines in the Expanded Programme on Immunisation (EPI) prevent nearly 4 million deaths each year¹⁶ and contribute to good antimicrobial stewardship. Robust immunization programs provide a positive return on public health investment, estimated to be US$54 for every dollar invested, including spillover social and economic benefits.¹⁷ Thus, localizing vaccine production closer to disease burden can help African countries respond better to the needs of their communities, provide more options to consumers, diversify the market, and shorten several parts of the supply chains.

Barriers to Vaccine Manufacturing in Africa: What Has Prevented It from Happening?

Unfortunately, the supply of COVID-19 vaccines to Africa follows a pattern of delayed access to essential and life-saving medical products that was also acutely felt during the HIV/AIDS and Ebola epidemics.¹⁸ A similar scenario is evident in access to the vaccine effective against Mpox, despite Africa being the only continent where the disease is known to be endemic.¹⁹ Breaking this cycle will necessitate reducing African reliance on medicines imported from
countries with facilities and knowledge, enabling the continent to meet the needs of its own citizens. The current push to self-sufficiency requires the alignment of numerous stakeholders and strong partnerships across multiple sectors.

**Vaccine Complexity**

Biologic products, such as vaccines, are characterized by their inherent complexity involving multiple components and multifaceted bioprocessing operations. Traditional vaccines often require growth of bacteria or viruses to express the antigen that is then purified and combined with other components, possibly an adjuvant, to produce an efficacious vaccine. Vaccines based on messenger ribonucleic acid (mRNA) technology, as was rapidly developed for SARS-CoV-2, are simpler for antigen generation yet bring a unique set of technical challenges to manufacturing. Challenges include the need for large amounts of specialized building blocks; the lack of well-established, scalable purification platforms; and the instability of the drug substance. Messenger RNA vaccines may also require formulation with lipid nano-particle delivery systems.

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The complexity of vaccine manufacture requires upfront investment in dedicated facilities, specialized equipment, and a skilled work force. The manufacturing processes and facilities for all vaccines also need to meet international best practices (i.e., current good manufacturing practices). This investment may limit the number and speed of new manufacturers in Africa. The main cost drivers include the high fixed costs associated with obtaining and often importing new manufacturing equipment, technologies, and materials appropriate for a large number of diverse production steps, as well as building and maintaining adequate facilities that operate under and adhere to current standards.  

**Workforce Capacity**

Few universities on the African continent provide curricula designed to support the vaccine ecosystem—biomanufacturing, bioengineering, or regulatory affairs. Often, African manufacturers need to focus on getting a biosimilar product to market rather than on the research that will expand their pipeline of new vaccines. The upstream manufacture of vaccines, drug substance generation, and purification, coupled with formulation, requires unique skills different from producing other medical products. This points to the immediate need for building workforce capability not only through formal education, but also via technical assistance and hands-on training, posing an additional cost burden. Established protocols, tools, and processes for technical and clinical R&D are also lacking, along with a workforce that understands best practices; regulatory aspects; and local, regional, or international regulations and guidelines that ensure that facilities and products meet necessary standards for registration or WHO prequalification.

Expanding manufacturing capacity also necessitates regional- or country-level expertise in the international regulations and guidelines that support the authorization of vaccine manufacturing facilities and registration of biologic products. Globally, fewer than 30 percent of National Regulatory Authorities (NRAs) have been found to function well according to the WHO maturity level (ML) classification system aligned with the Global Benchmarking Tool. On the African continent, WHO ML3 for imported and distributed vaccines has been achieved by Ghana, Nigeria, and Tanzania, while Egypt and South Africa have reached ML3 for the regulation of vaccines manufactured, imported, or distributed in their countries. Regulation of vaccines according to international standards is essential for access to safe, effective, and quality vaccines; thus, further workforce development is required.

**Limited R&D and Drug Substance Capabilities**

Sovereign vaccine manufacturing requires end-to-end integrated production. Where vaccine capabilities exist in Africa, many manufacturers have limited infrastructure, technical capacity, or resources to support the R&D that

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— Michel Sidibe, Africa Union Special Envoy for the African Medicines Agency.

The COVID-19 pandemic has exposed our continent’s vulnerabilities in ensuring access to vital drugs, vaccines, and health technologies. — Michel Sidibe, Africa Union Special Envoy for the African Medicines Agency.
promotes advances in vaccine technology. The R&D capabilities and facilities that enable drug substance production and complex formulation are few on the continent. As a result, current manufacturers are delivering doses predominantly in the fill and finish, labeling, and packing of imported drug substances, or repackaging and distributing imported vaccines. The expansion of upstream vaccine production necessitates additional facilities and equipment, along with technical expertise and regulatory oversight; expansion of these activities is ongoing but will require time to become fully functional. Novel process and analytical technologies, as well as clinical development knowledge, require third-party technical assistance to build competencies, without which Africa will remain reliant on technology transfer and licensing agreements with innovator companies. Investment in local R&D as well as manufacturing facilities may also enable development and access to vaccines for African-specific diseases that are unlikely to be a priority of the larger pharmaceutical pipelines.

Budding National Regulatory Authorities

A country’s NRA plays a central role in ensuring access to safe and quality-assured marketed vaccines. African countries are looking to build their regulatory capacity for licensing biologic products and associated activities based on guidance and regulations in compliance with best practices. The lack of a mature, coordinated, and efficient regulatory ecosystem across the African continent necessitates that a single product’s manufacturer may need to seek approval from the respective regulatory authorities of 54 countries, each with varying requirements. Not only does this repeated effort delay the introduction of new products, but it may also dissuade manufacturers from seeking the needed licensure for wider vaccine implementation. Regulatory harmonization across the continent via the African Medicines Agency (AMA) is an important ambition.

Strengthening of regulatory expertise is necessary across the supply chain, including facility inspection, facility authorization, and product dossier review and approval. The latter necessitates comfort in the evaluation of biologic products, which for vaccines includes drug substances and drug products developed using different vaccine technologies as well as adjuvants. The dossiers also include comprehensive information and non-clinical and clinical data that must be reviewed. Following vaccine distribution and implementation, skills in post-marketing surveillance and pharmacovigilance are necessary to ensure vaccines meet the expected standards. NRAs that lack experience with clear and efficient science-based regulatory pathways, guidelines, and procedures are at a disadvantage.

National Control Laboratories’ Unfamiliarity with Vaccine Lot Release

NRAs rely on independent testing by national control laboratories (NCLs) across the life cycle of a medical product, including lot release, market authorization, and post-marketing surveillance. NCLs in Africa may lack the necessary, specialized, and calibrated equipment to evaluate the wide range of analytical and in-vitro testing that may be required for biologic products and by different vaccine platforms. To support expanding African vaccine manufacturing, a parallel increase in equipment, accessories, and consumables required by each NCL is also necessary. To achieve international accreditation, each NCL needs not only a quality management system with updated processes in compliance with WHO and other relevant guidelines, but also procedures to execute core activities and standard operating procedures (SOPs) for activities such as receiving, storing, handling, and transporting samples. These labs also may not have sufficient, knowledgeable human resources and require workforce capacity building.

Supply Chain Challenges

Challenges in procurement of raw materials, insufficient manufacturing materials, inadequate cold chain control for certain vaccines, and lack of supplementary supplies (e.g., syringes) and related services (e.g., biohazard waste disposal) all hinder the expansion of vaccine manufacturing
and distribution. Cold chain requirements and the associated logistical challenges throughout the supply chain can also be a major barrier to delivering vaccines, especially to rural areas. While local cold chain challenges can remain, moving manufacturing closer to the point of use can additionally support vaccine delivery to mitigate distribution challenges.

**Financing, Market Dynamics, and Partnerships**

Expansion of facilities, infrastructure, and technical knowledge is a time-consuming and costly endeavor. The International Finance Corporation (IFC) estimates that close to $60 billion is needed to expand local African manufacturing capacity to meet the expected vaccine demand for the continent based on the growing population. African-based manufacturers have and may continue to face a financial burden associated with the necessary expanding infrastructure and knowledge excellence. In the absence of self-financing, they are reliant on outside investments or access loans with reasonable interest rates and terms. While the urgency of the COVID-19 pandemic has opened access to substantial capital, an increase in favorable financing options is needed to make the sector sustainable. Recently, the Program for Appropriate Technology in Health (PATH) estimated that a minimum of 12 vaccine manufacturing plants and at least 12,000 highly trained employees will be needed to meet current African vaccine requirements and the Partnerships for African Vaccine Manufacturing (PAVM) 2040 goal. Strong partnerships and efforts to de-risk these investments are needed to justify the sizable investments that expanding vaccine production requires.

In addition, insufficient incentives and uncertain procurement mechanisms make it challenging for manufacturers to justify investment in new vaccine capabilities or production lines, particularly because African vaccine manufacturers face stiff competition from established large vaccine manufacturers located in other parts of the world. Political leadership and public health policies are needed from national governments to foster a healthy, sustainable market for African vaccines.

**Global Response to Expand Vaccine Production Capacity Across Africa**

As a result of the COVID-19 pandemic and subsequent medicines disparity, several new initiatives have been put in place that enable international financing and technology cooperation with the low-income regions of the world. At the start of 2020, only two African countries had COVID-19 testing capacities. Currently, all 54 countries have this capability. This is one example of the numerous public health system strengthening efforts undertaken by many organizations, including the ACT Accelerator, the Pandemic Supply Chain Network, the United Nations COVID-19 Supply Chain Task Force, USP projects and many government donors.

The AVAT, sponsored by a number of global African leaders and COVAX, have worked to secure COVID-19 vaccine doses with the hope of attaining a targeted immunization of 60 percent of the African population. AVAT has partnered with the UN Children’s Fund (UNICEF) to procure and deliver vaccines on behalf of African Union Member States. Procurement of vaccines has been made possible with support from the African Export-Import Bank (Afreximbank), and an Advance Procurement Commitment Guarantee. This model may pave the way for African pooled procurement of commonly used vaccines as part of their routine immunization programs. For countries graduating from Gavi funding, this route to affordable vaccine access may become particularly important.

In 2021, WHO established an mRNA technology transfer hub to help scale-up global manufacturing. WHO-supported technology transfer hubs have successfully boosted the production of vaccines for other diseases, such as influenza. Focusing on COVID-19 vaccines, the WHO mRNA hub, located in South Africa, serves multiple “spokes” globally—six located in Africa—to transfer technology and provide training on potential vaccines amenable to mRNA technology.
to interested manufacturers in LMICs. In 2022, WHO also created a global biomanufacturing training hub. This center, located in South Korea, will serve countries wishing to produce their own vaccines and other biologic medicines, mainly produced until now in high-income countries.

Several bilateral agreements have enabled COVID-19 vaccine manufacturing to be conducted on the African continent. In 2022, Johnson & Johnson partnered with South African drugmaker Aspen Pharmacare Holdings Ltd. to undertake fill and finish activities of its drug substance and supply the COVID-19 vaccine to all African countries. In mid-2022, Pfizer and BioNTech brought the Biovac Institute (South Africa) into their global COVID-19 vaccine manufacturing network. Building on its development efforts during the pandemic, BioNTech has been able to miniaturize the processes for mRNA drug substance and formulation into modular units. These modular factories are intended for Africa and the production of mRNA vaccines beyond COVID-19. More recently a subsidiary of Aspen finalized an agreement with the Serum Institute of India to manufacture, market, and distribute four routine vaccines (pneumococcal, rotavirus, polyvalent meningococcal, and hexavalent) for Africa. The initial technology transfer includes formulation and fill and finish using bulk drug substances supplied by the Serum Institute.

Recently, a group of European and African international donors announced contributions of more than €100 million in funding to support manufacturing and capacity building in Africa. These funds are targeted to support the AMA and other African regulatory initiatives to strengthen Africa’s regulatory capacity and improve access to quality, affordable drugs and vaccines across the continent.

Calls to Action: What More Is Needed to Make Vaccine Manufacturing in Africa a Reality?

With 54 member countries, the African continent has a diverse set of needs and wide gaps among countries in terms of vaccine manufacturing capacity, regulatory environment maturity, market size, and growth trajectory. COVID-19 vaccine inequities have prompted Africa to become more self-reliant in meeting local needs, and the world to be more responsive to local contexts and demands. As such, there is growing momentum for expanding existing local manufacturing capacity and ensuring the current investments following the COVID-19 pandemic are optimized. In the short term, expanding vaccine manufacturing and extending end-to-end production capacity can help address and prepare for the next pandemic. Local vaccine manufacturing and R&D also can address African-specific diseases and vaccine-preventable illnesses, such as MMR, HPV, and DPT.

Building on better understanding of the barriers, the following actions are proposed to position African vaccine manufacturing for enhanced sustainability.

Catalyze Technical Assistance

Actions: After defining gaps in manufacturing facilities and skill sets, technical assistance must focus on developing a comprehensive plan for managing not only the transfer of technology, but also the development of workforce and knowledge to build the capacity of the receiving organization, whether it is a manufacturer, regulator, or control testing laboratory.

Enablers: Building an experienced workforce begins with expanding educational opportunities within African universities and extends to establishing regional centers of excellence developed to retain and train local talent.
Investing in workforce development needs to include translational R&D educational programs so that industry can draw upon a labor force with knowledge in biologic manufacturing and the ability to rapidly apply experiences to the production and scale-up of vaccines, including new platforms such as mRNA technology. Specialized training is also needed in high-end technologies and analytics that are indispensable for formulation efforts. Training needs to be in accordance with WHO standards and International Council for Harmonisation (ICH) guidelines.

Technology assistance can bridge gaps in knowledge and innovative manufacturing practices, whether in the process, analytic testing, equipment, or knowledge. It involves sharing not just technology and knowledge to elevate and optimize output, but also processes that adhere to current GMP to ensure efficient and quality vaccine development. Support for technology transfer relies on using gap analyses, facility assessments, and other data to develop and implement an adapted transfer protocol to bridge and manage the transfer of knowledge and skills from one manufacturer to another.

Third-party technical assistance can facilitate technology transfer and the assessment of required investments in infrastructure. This support is wide ranging and can include advising manufacturers on sourcing vaccine manufacturing equipment for aseptic drug substance production, formulation, and filling, including vials, stoppers, and syringes as well as cold chain requirements for effective “last-mile” distribution. Further technical assistance to African vaccine manufacturers can be provided for the development of long-term strategic business plans by conducting market assessments and understanding the market landscape and potential roadblocks.

**Enhance Vaccine Manufacturing Strategies**

**Actions:** Through assessments and feasibility studies, NRAs and other stakeholders can determine the level of a manufacturer’s readiness to initiate or expand vaccine production. This can inform policies, regulatory guidelines, and infrastructure and workforce needs that are necessary to support a burgeoning vaccine manufacturing sector.

Bolstering and expanding capacity and facilities start with the strategic vision that develops business processes and pipelines for the continual use of improved facilities and distribution of expanded vaccine supplies. Policies jointly developed by governments and public health stakeholders need to prioritize immunization programs and determine which vaccines should be utilized and which will be procured to address the local and regional need and context. Current and robust local disease burden context requires data-driven input from the academic medical and R&D communities as well as applicable information from nongovernmental organizations. This clarity of vision for regional or national policy and long-term public health strategy further supports and sustains manufacturers’ and regulatory authorities’ institutional development plans.

**Enablers:** Meeting the African continent’s vaccine needs will require a strong supply chain with reliable delivery of locally produced raw materials and ancillary goods, where possible, that can be used by local manufacturers to consistently produce large numbers of doses. This will need to be coupled with progressive phasing of expanded expertise and facilities from fill and finish to formulation and to drug substance manufacture. In parallel with expanded expertise, scale-up of production capacity will be required. The evolving competencies and technologies will also require state-of-the-art equipment and labs able to undertake the required analytical and release testing.
Diversification of manufacturing competencies, vaccine technologies, and products should be strategically defined and distributed across the continent to optimize product availability, market share, and sustainability. Through appropriate convergence, Africa could develop a robust network of centers of excellence where clear business strategies map out the efficient use of available resources to support public health growth and align with government targets and objectives for needed vaccines. For optimal harmonization across the continent, stakeholders can leverage existing thinking within the PAVM framework or Pharmaceutical Manufacturing Plan for Africa to develop country-focused and tailored policies, guidelines, and milestones to support sustainable, local manufacturing.

**Strengthen Regulatory Systems**

**Actions:** The engagement and support of LMIC governments is needed for continued growth and recognition of responsible regulatory authorities and their critical functions for vaccine production and distribution. A strong regulatory agency harmonized to both African and international standards can facilitate an expedited review pathway of dossiers and registration decisions for new vaccine authorization and independent lot release, assuring availability of safe and quality vaccines and the identification of substandard or falsified products before they are delivered to populations.31 The AMA was created with the task of harmonizing the regulation of medicines and pharmaceutical manufacturing across the African Union and reducing dependency on non-African countries for health security. Fully operationalizing the regulatory oversight capabilities of this organization will require enhancing strategic partnerships with the national and regional efforts across the continent, which began under the African Union Development Agency’s African Medicines Regulatory Harmonization initiative. Effective regulation of the market and aligned procedures endorsed by African governments is key to the delivery of quality medical products. Thus, regulatory harmonization efforts need to define clear, efficient, and science-based pathways.

**Enablers: National Regulatory Authorities**

NRAs with a high level of maturity help ensure access to quality vaccines, medicines, and other medical products. NRAs ensure that only authorized facilities are licensed and vaccines are registered and distributed through health care systems, while also tracking the safety and efficacy of vaccine products through pharmacovigilance. New vaccines, whether produced locally or imported, must meet manufacturing quality standards established by bodies such as WHO or well-functioning regulatory authorities. Well-informed NRAs can and will play a key role in helping to reduce registration times so that safe and effective vaccines can be distributed quickly—especially important during a pandemic. To this end, a greater number of African agencies aim to enhance their WHO Global Benchmarking Tool ML to ensure the quality, safety, and efficacy of the vaccines used in their country. The African NRAs that have achieved ML3 provide a foundation to assist others on the continent with their aspirations toward stronger regulatory systems.

The newly established AMA can also play a key role in ensuring a harmonized and integrated regulatory pathway, a framework for harmonized oversight of new products, and continual improvement. Locally relevant guidelines and SOPs for inspections and technical dossier assessments will need to be developed for vaccines and biologic products. The AMA also can play a critical role in establishing joint regulatory authorities’ review of a product, an accelerated review process, or emergency use authorization; each process can expedite approval times for new vaccines to better respond to outbreaks and pandemics.32 Strong African regulatory authorities, whether by country, region, or continent, will ensure the appropriate public health positioning of vaccines, including policies, procedures, and legal guidelines required to ensure quality.
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National Control Laboratories that meet international requirements consistent with laboratory practices provide an impartial assessment of vaccines to ensure safety and quality prior to market authorization. Regulatory authorities may depend upon this critical service to assess vaccine variations in existing marketing authorizations, post-marketing surveillance, and provide lot release approvals.

Concerted support is important to ensure that African NCLs, as required, have the ability to meet the international standards for accreditation. Beyond qualified human resources and validated equipment, the NCLs will need support to ensure the operation of quality management systems, enabling compliance with WHO, other relevant guidelines, and SOPs to execute core activities, such as receiving, storing, handling, and transporting samples. NCLs in Africa can leverage the guidance document offered by the Africa CDC which provides information on developing a national laboratory quality framework. Laboratories can take advantage of the document to create quality management systems while policy makers can use the recommendations to establish or amend national policies and strategies. 33

Leverage the Role of Governments and Stakeholder Collaboration

Actions: The important role of African governments is often underestimated. Engaged political leaders are necessary to provide their support needed not only in adopting and implementing favorable public health policies, including national immunization plans, but also for the commitments needed to support the longer term strategies of the manufacturing industry and regulatory bodies. Once Africa can assure that all medical products, whether locally manufactured or imported, meet international standards of safety, quality, and efficacy, sovereign manufacturing sectors can become sustainable and provide the African population timely access to lifesaving vaccines. Greater vaccine sustainability requires significant investments from country governments and less reliance on donor initiatives.

Enablers: In establishing and implementing policies and regulations, governments will need to create favorable incentives and market environments to support the growth of vaccine manufacturing within African countries. Incentivized local manufacturing may require favorable tax policies that promote appropriate investments in infrastructure as well as policies that include local purchase commitments and a guaranteed market to investors. Establishing multiple stakeholder collaborations, including immunization programs and public and private health systems, may work to facilitate vaccine access and thus meet market need. Innovative financing through public and private partnerships may provide a pathway for manufacturers to access alternate sources of capital to advance their vaccine production capacity and distribution network. The financing mechanism can include favorable loan terms, ideal financial structures, and loan instruments.

Summary

Policies jointly developed by local governments and public health stakeholders will need to prioritize immunization and identify which vaccines, if produced, are likely to address the local and regional need and context. This information can feed directly into the manufacturer’s strategic business plans. Equally important, the previously defined robust African regulatory framework will build public confidence in drugs produced in Africa for Africans, identify fake and counterfeit products, and create the necessary conditions for the stronger domestic medical manufacturing sector needed for future pandemics and disease outbreaks.
### Calls to Action and their Anticipated Impact

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<th>ACTIONS</th>
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| Catalyze Technical Assistance | • Trains, expands, and retains the intellectual knowledge base of the workforce necessary to sustain all disciplines within the vaccine ecosystem.  
• Provides independences for Africa to pursue its own vaccine development agenda and meet its needs. |
| Enhance Vaccine Manufacturing Strategies | • Reduces competition, optimizes collaboration, and enhances manufacturers’ self-reliance and sustainability.  
• The manufacturing capacity for local and regional distribution or export reduces the African dependency on imported vaccines. |
| Strengthen Regulatory Systems | • Continental harmonization of regulatory requirements streamlines the approval process for vaccine manufacturers.  
• Enhanced knowledge base and efficiency of NRA and NCL increases trust in vaccine authorization among African countries. |
| Leverage the Role of Governments and Stakeholder Collaboration | • Facilitates country, regional, and continental vaccine needs and production strategies are aligned across all public health sectors  
• Guides the short-term and long-term objectives of national immunization plans and supports sustainable expansion of manufacturing across Africa that is not dependent solely on donor funding. |
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What you can do

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**About USP**

USP is an independent, international, and scientific nonprofit organization focused on building trust in the supply of safe, quality medical products. We are working to strengthen the global supply chain so the medicines and other products people rely on for health are available when needed and work as expected. USP has 16 offices across 13 countries and implements global health programs in 40+ countries worldwide.