# Clinton Health Access Initiative, Inc.

## Continental Market-shaping Strategy for a Sustainable Vaccine Manufacturing Footprint in Africa

Vaccine Markets Team November 2023



## Key Takeaways

- The inequitable rollout of COVID-19 vaccines drew global attention to the lack of vaccine manufacturing capacity in Africa. Significant political and financial investment has now been made in African vaccine manufacturing, creating significant growth momentum behind the industry.
- Stakeholders in the global health ecosystem have three major objectives when it comes to the expansion of African vaccine manufacturing: improved pandemic preparedness and response (PPR), robust global market health, and commercial viability of manufacturers. Our analysis offers a view on how to target a compromise between these objectives.
- Our target identifies a market-size of three to five geographically dispersed manufacturers within Africa to meet these objectives. To provide comprehensive coverage during a potential pandemic, this manufacturing footprint should target end-to-end production capacity of approximately 170 million doses per annum across eight identified antigens and nearly 460 million doses per annum of additional antigen-agnostic Drug Product (DP) capacity.
- The current manufacturing landscape indicates four major risks to achieving this target:
  - 1. Vaccines are likely to be costly to produce initially, risking low uptake, due to structural cost disadvantages.
  - 2. The current footprint of African vaccine manufacturing exceeds the target for DP capacity and annual African vaccine demand with the majority of installed DP capacity sitting idle due to lack of tech transfers, while current Drug Substance (DS) capacity is far lower.
  - 3. Governments have taken limited steps to procure African-made vaccines, making future manufacturing and demand vulnerable to high-production costs.
  - 4. The enabling environment does not yet optimally support vaccines to reach the African market, including regulatory agencies across the continent that may vary in their capacity to meet international standards.
- To address these market risks and achieve a sustainable manufacturing footprint, five intervention areas have been identified:
  - 1. Stakeholders should be aligned on a realistic target to enable better coordination and enhance chances of success.
  - 2. Manufacturers should be appropriately financially incentivised to enhance their cost competitiveness.
  - 3. Technology transfer partnerships should be facilitated to expand African DS capacity and ensure the use of existing DP capacity.
  - 4. Policy provisions should be made to ensure demand materialises for African-made vaccines.
  - 5. An enabling environment should be facilitated to enhance African vaccine manufacturers' global competitiveness.

In this whitepaper, we outline a continental market-shaping strategy for a sustainable vaccine manufacturing footprint in Africa to improve health outcomes and save lives. We outline a target, then compare this target to the rapidly evolving situation on the ground today in order to identify strategies to achieve a sustainable manufacturing landscape.

In so doing, this whitepaper aims to present a balanced view of African vaccine manufacturing, and build on the growing literature on this subject to achieve three objectives:

- 1. Outline a target for a sustainable African vaccine manufacturing footprint grounded in public health objectives.
- 2. Identify key risks to the achievement of this target.
- 3. Outline the market-shaping interventions required to mitigate these key risks, acknowledging the work already underway by various partners, and identifying action-oriented solutions to the remaining gaps.

This whitepaper complements our <u>recent briefing</u>, coauthored with Africa CDC and PATH, where we examine current and planned vaccine manufacturing capacity in Africa.

## 1. Background and Context

Deep structural inequalities in global health markets led to a glaring disparity in the distribution of COVID-19 vaccines in the initial days of the pandemic. Many wealthy countries offered citizens third or even fourth booster shots while hundreds of millions of people in lower-income countries were still waiting for their first dose.<sup>1</sup> In Africa this imbalance was especially pronounced. The continent lagged significantly behind the rest of the world in vaccination rates in part because less than one percent of all vaccines administered in Africa in any given year are manufactured on the continent, while the rest are imported.<sup>2</sup>

History has shown that export restrictions, hoarding, and nationalism often surge during pandemics. For example, over the past two decades the fear of pandemic influenza has moved wealthier countries to buy virtually all available pandemic flu vaccines and prohibit their export.<sup>3</sup> Similarly, during the COVID-19 pandemic vaccine-producing countries imposed restrictions on exports of vaccines and critical raw materials.<sup>4</sup>

With end-to-end (drug substance and drug product) vaccine manufacturing capacity on the continent, African countries can increase their resilience against future pandemics and mitigate the vulnerabilities associated with global supply chain disruptions. Beyond timely responses to health crises, self-reliance in vaccine production can also spur local economic growth, technological progress, and foster global collaboration in health research and development.

<sup>&</sup>lt;sup>1</sup> WHO Coronavirus (COVID-19) Dashboard

<sup>&</sup>lt;sup>2</sup> "Scaling up African vaccine manufacturing capacity." Wellcome Trust, January 2023. Wellcome-Biovac-BCG-Scaling-up-African-vaccinemanufacturing-capacity-report-2023\_0.pdf.

<sup>&</sup>lt;sup>3</sup> "From private incentives to public health need: rethinking research and development for pandemic preparedness," The Lancet, Aug 2023

<sup>&</sup>lt;sup>4</sup> "Export restrictions do not help fight COVID-19," UNCTAD, June 2021

The two critical steps needed in the vaccine manufacturing process are:

- 1. Drug substance production (DS): Producing the active vaccine component (or, antigen), which is the most cost-intensive and technically challenging step; and
- 2. Drug product production (DP): Producing the final vaccine product, which includes formulation, fill, and finish (form/fill/finish).

Given the potential benefits of vaccine production on the continent, over US\$4.5 billion has been pledged and political commitment has increased to advance the vaccine manufacturing ecosystem.<sup>5</sup> The African Union and Africa Centres for Disease Control and Prevention (Africa CDC), through the Partnership for African Vaccine Manufacturing (PAVM) initiative, have set a goal that 60 percent of all vaccines used on the continent should be African-made by 2040.<sup>6</sup> Furthermore, Gavi, The Vaccine Alliance is updating its global healthy market criteria to emphasize regional supply diversification, and is expected to launch a targeted financial instrument to support vaccines manufactured on African soil.<sup>7</sup> As Gavi accounts for roughly half of all Africa's vaccine procurement by value, this commitment is expected to have a large impact.

While the promise of continental vaccine manufacturing growth is alluring, there are challenges. These challenges must be addressed to ensure the burgeoning sector can thrive in the long term.

- The proliferation of ~30 new vaccine-producing initiatives raises the risk of overcapacity and commercially unsustainable projects on the continent. This must be dealt with head-on to eliminate the unwarranted perception that Africa's vaccine initiatives cannot succeed—which is a challenge in and of itself.
- The current lack of clear commitment from governments to buy African-made vaccines may hinder the sector's expansion and the region's move towards greater health security and self-reliance.
- The support for more regionalized vaccine manufacturing efforts to prepare for a next pandemic may jeopardize the progress made in the last two decades by the global health sector in providing consistent, affordable routine vaccine supplies to low- and middle-income countries.

## 2. A Target Pathway for African Vaccine Manufacturing

Crafting a strategy for African vaccine manufacturing requires a clear-sighted target. The growing interest in the sector has seen a number of such targets outlined by partners at national and regional levels, most notably Africa CDC's aforementioned target of 60 percent of all vaccines used on the continent to be African-made by 2040.<sup>6</sup> This top-down, politically-oriented target has achieved significant impact by catalyzing momentum, but leaves open questions about what type of manufacturing should be prioritized and the potential impact of this production capacity.

To address these questions and outline a view on a sustainable fit-for-purpose African vaccine manufacturing footprint, CHAI worked in close collaboration with many ecosystem partners to outline a target. The results are a bottom-up analysis of three public health objectives, which taken together can form a target pathway to complement Africa CDC's target.

<sup>&</sup>lt;sup>5</sup> CHAI Analysis of funding commitments (not reflective of actual cashflows), June 2023

<sup>&</sup>lt;sup>6</sup> PAVM, Framework for Action, March 2022

<sup>&</sup>lt;sup>7</sup> Gavi, Expanding sustainable vaccine manufacturing in Africa: Priorities for Support, November 2022

#### Objectives for a strong African vaccine manufacturing footprint

These objectives are:

- Pandemic preparedness. First, African vaccine manufacturing should enhance equitable access to vaccines and pandemic preparedness on the continent such that the inequities experienced during COVID-19 do not occur again. While developing manufacturing capacity across all platforms may have benefits in the event of another pandemic, this objective requires targeting manufacturing platforms that have a proven ability to rapidly scale up the production of pandemic-appropriate vaccines. CHAI here aligns with the Coalition for Epidemic Preparedness Innovations' (CEPI) identification that mRNA, recombinant protein, and viral vector platforms should be prioritised for this purpose.<sup>8</sup>
- Global Market Health. Second, African vaccine manufacturing should safeguard, if not improve global market health, being careful not to compromise affordability and availability of key lifesaving vaccines. New entrants into some antigen markets may have negative externalities of price increases or supply security issues, which ultimately may undermine vaccine access. To avoid this, African manufacturers may consider novel antigen markets or existing markets where their entry will facilitate healthy competition, stable prices, and supply security.
- **Commercial viability.** Lastly, African vaccine manufacturing should be commercially viable in the longterm, ensuring this strategic industry is sustainable and supports economic development. Therefore, it must aim to achieve economies of scale and not rely on significant perpetual subsidies from governments and donors. Within the constrained health budgets of many national governments and amid the competing priorities of a growing number of international donors, an overreliance on these sources risks funding being diverted away from other, potentially more lifesaving areas of expenditure toward African-made vaccines.



Figure 1: Target pathway for a fit-for-purpose African vaccine manufacturing footprint

For end-to-end African vaccine manufacturing to be sustainable and beneficial, it should support both pandemic preparedness and vaccine market health<sup>9</sup>, bringing benefits during both pandemic and non-pandemic periods. Furthermore, while catalytic funding may be required to kick start the sector, continental manufacturing cannot rely on perpetual subsidies to deliver its products. Any manufacturing capacity that satisfies these criteria can be considered a desirable addition to the global end-to-end manufacturing landscape.

<sup>&</sup>lt;sup>8</sup> <u>CEPI, Delivering Pandemic Vaccines in 100 Days</u>, November 2022

#### Recommended footprint size for success

In order for the sector to succeed, our analysis indicates an African vaccine manufacturing footprint of around 170 million doses end-to-end manufacturing capacity per annum by 2030 would be desirable. Priority antigens for end-to-end manufacturing include yellow fever, oral cholera, malaria, measles-rubella, meningococcal and pneumococcal conjugate, as well as novel antigens relevant to the African market (i.e., RSV, TB).

For Drug Product (DP), commonly referred to as Fill & Finish, manufacturing any antigen can be undertaken in a way that has marginal impact on global vaccine market health and may be sustainable when grouped with other production. To approach target-setting for DP then, the most significant constraining factor is the contribution of the manufacturing capacity to pandemic preparedness targets. Here, many targets could be considered, but we have aligned to WHO's influenza pandemic preparedness target: manufacturing two doses for 70 percent of the population, ensuring 100 percent coverage for vulnerable groups.<sup>9</sup> Given DP capacity can be significantly increased during emergencies, such as a pandemic,<sup>10</sup> a total routine DP capacity of 630 million doses per annum by 2030 could theoretically enable 2.4 billion doses for Africa in emergency situations. Therefore, DP capacity in Africa of up to 630 million doses per annum would be a desirable.

Together, this suggests a balanced target of about 460 million doses annually of antigen-agnostic DP capacity, and 170 million annually of continental end-to-end manufacturing capacity to satisfy the three objectives outlined above. This combined projected annual capacity of approximately 630 million doses by 2030 fulfils close to 40 percent of Africa's anticipated vaccine demand for that year and aligns approximately towards Africa CDC's top-down 60 percent target of vaccines administered in Africa by 2040 being locally produced. CHAI'S bottom-up analysis enables a closer link between the target and the objectives outlined, with greater detail in terms of desirable antigens and types of manufacturing, thereby grounding the ambition of African vaccine manufacturing in clear public health benefits as well as political ambitions.

Our analysis leads to several considerations, based on these capacity targets and the objectives outlined above, which will ground the ambition of African vaccine manufacturing in clear public health benefits.

- 1. The market opportunity points to the **viability of three to five manufacturers geographically dispersed** on the continent. This is substantially less than the 30 new initiatives currently in development.
- 2. Given the limited market opportunities, it may be prudent for African manufacturers to minimize competition with each other in established antigen markets.
- 3. Manufacturers are encouraged to **diversify their vaccine portfolios rather than focusing on one antigen**, to ensure they are resilient against market shifts and aligned with broader healthcare needs.

This analysis can help guide stakeholders to align their existing and planned initiatives for further development of the African vaccine manufacturing ecosystem. In so doing, the sector will be far more likely to achieve desirable public health outcomes. In the next section, we will discuss the risks that could impede achievement of this target for vaccines made in Africa.

<sup>&</sup>lt;sup>9</sup> The Global COVID-19 Vaccination Strategy in a Changing World:, WHO (2022)

<sup>&</sup>lt;sup>10</sup> DP production capacity can be increased 4x in emergencies as a result of 2 factors: ~65% increase in capacity by shifting from standard operations (216 days/year, operating 12 hrs/day) to emergency operations (267 days/year, operating 16 hrs/day) and ~130% further increase in capacity from shifting to 10 dose vial size.

## 3. Market Risks to Achieving the Target Pathway

While our analysis has outlined a theoretical target for an African vaccine manufacturing footprint, several challenges exist in the landscape that may obstruct achieving this goal. The most pronounced of these risks are the high cost of production, a mismatch between planned production capacity and demand, a lack of policy support from governments, and a weak enabling environment.

#### High cost of production

African vaccine manufacturers face substantial market risk due to structural cost disadvantages when competing with established developing country manufacturers, particularly in India. Capital expenditure (CAPEX) for construction of high-tech manufacturing facilities is estimated to be between 40 and 70 percent higher in Africa than India.<sup>11</sup> African manufacturers also face an operational expenditure (OPEX) cost disadvantage due to the high cost of imported raw materials and consumables, as well as higher labor costs, which can be three times higher in Africa than India.<sup>12,13</sup> Furthermore, industrial policies in Africa, such as limited local tax incentives and strict import rules, lead to extra customs costs for certain consumables (e.g., bioreactor bags) and raise African vaccine production costs, hindering global competitiveness. Interventions are in progress to help address these initial cost disadvantages, but the current situation suggests African vaccine manufacturers should expect to come to market with prices higher than international comparators, risking uptake of their vaccines and therefore, their long-term viability.

#### Mismatched production capacity and limited utilization

There are mismatches between the installed and planned capacities and the desirable manufacturing target outlined above. In the short-term, we observe significant overcapacity for DP manufacturing. Existing installed capacity on the continent is around 2 billion doses, far exceeding both the total projected 2030 African demand of 1.5 billion doses and the target capacity of 630 million (as noted in **Figure 2**). While some of this capacity can be used for other products (e.g., Insulin), this is unlikely to address the overcapacity. Should expected DP capacity expand to four billion doses per year, based on current manufacturer construction plans,<sup>14</sup> we can expect even more idle capacity.

The situation is further exacerbated by the fact that more than 60 percent of installed DP capacity lacks a confirmed technology transfer to bring a vaccine product to market. Originators have been slow to engage in technology transfer agreements, often due to the perceived reputational risks in engaging in technology transfers with new manufacturers when there is limited financial benefits for their efforts. Additional challenges including trade restrictions on upstream supply of raw materials, skilled workforce, supply chains, and cost.<sup>15</sup> Without interventions to mitigate these challenges, DP capacity is likely to remain unutilized, becoming a drain on the finances of companies and impeding the achievement of ecosystem objectives.

In the longer term, end-to-end manufacturing capacity is likely to be key for manufacturers to achieve commercial viability. At present, there are limited future expansion plans of end-to-end manufacturing capacity, meaning the current ecosystem falls short of the objectives outlined in enhancing pandemic preparedness and response in the long run. Furthermore, some end-to-end capacity is being developed for antigens such as inactivated polio vaccine (IPV) and platforms such as whole pathogens that don't align with pandemic preparedness needs or market health priorities. While the lack of end-to-end manufacturing capacity may be

<sup>&</sup>lt;sup>11</sup> Turner and Townsend Market Survey, July 2022

<sup>&</sup>lt;sup>12</sup> Internal Benchmarks and UN Database, Employment and Wages by Industry Data on 'Chemical and Chemical Products' Industry

<sup>&</sup>lt;sup>13</sup> BMGF report; CHAI Analysis

<sup>&</sup>lt;sup>14</sup> Current and planned vaccine manufacturing in Africa, Results from a joint assessment by Africa CDC, CHAI, and PATH, September 2023

<sup>&</sup>lt;sup>15</sup> Technology Transfer: A Collaborative Approach to Improve Global Health, IFPMA, December 2021

addressed over time, market-shaping interventions are required to accelerate the backwards integration of manufacturers from drug product into drug substance in-line with the target pathway.



Figure 2: Current and future DP capacity vs. 2030 demand and target pathway, doses (M)

#### Lack of procurement policy support for African-made vaccines

A basic requirement to achieving a sustainable vaccine manufacturing footprint is sufficient demand for the vaccine output. Learning from the history of vaccine manufacturing in countries such as Brazil, China, India, and Indonesia, a common lesson can be learned: procurement commitments from governments have been crucial in supporting the growth of locally manufactured vaccines. As it stands, commitments of African governments to actively support procurement of African-made vaccines are unclear, particularly if they are more expensive than alternate options, as is likely to be the case.

To ensure manufacturers achieve competitive scale and economic viability, a continental market approach is crucial in Africa. While Indian and Chinese manufacturers are backed by a huge domestic market, African manufacturers will need to either serve demand across the continent to achieve economies of scale or seek procurement support from other regions. While the goal will be to serve the global market, it is unlikely initial commitments to overcome scale-up costs will come from bilateral procurers outside the continent; after all, they have their own vaccine industries to support. Therefore, ensuring sufficient demand for African-made products will almost certainly require African governments to implement continental or regional frameworks for preferentially procuring African-made vaccines. How to solve this risk remains an open question: what are the incentives for non-manufacturing countries to choose or procure African-made vaccines?

Currently, it's important to note that vaccine procurement in Africa receives significant support from global stakeholders. Approximately 90 percent of vaccine procurement is conducted through UNICEF, with Gavisupported vaccines accounting for roughly 50 percent of that volume with relatively modest country cofinancing.<sup>16</sup> While there is a significant shift on the horizon with six African countries representing nearly 26 percent of total African vaccine volume scheduled to transition out of Gavi support before 2030—the current Gavi/UNICEF system is likely to represent the majority of vaccine volumes used in Africa for some time to come. Within this system, in most cases, governments have the authority to select the vaccines for their national immunization program from a list of quality-assured options available on the Gavi menu. Therefore, the key to demand materialization for vaccines produced in Africa, lies in the inclination of African governments to procure these vaccines.

<sup>&</sup>lt;sup>16</sup> PAVM demand model built with Linksbridge data and CHAI analysis

In CHAI's assessment, the likeliness of African countries pursuing the preferential procurement of African-made vaccines varies significantly. Countries with strong existing vaccine manufacturing capabilities (e.g., South Africa & Egypt) predominantly support domestic manufacturers, with minimal clear intent to source from other African nations. Countries which are in the Gavi accelerated transition phase (e.g., Kenya and Nigeria) seem interested in backing manufacturers on the continent as a plan for vaccine supply post-Gavi support but may balk at the cost of doing so. Meanwhile, procuring African-made vaccines appears to be a lower priority for countries which will continue to receive Gavi co-financing for some time to come (e.g., the Democratic Republic of Congo and Tanzania). Coupled with constrained health budgets across the continent and competing health priorities, significant alignment is required for countries to agree to the preferential procurement required to support economies of scale for African manufacturers.

#### Weak enabling environment

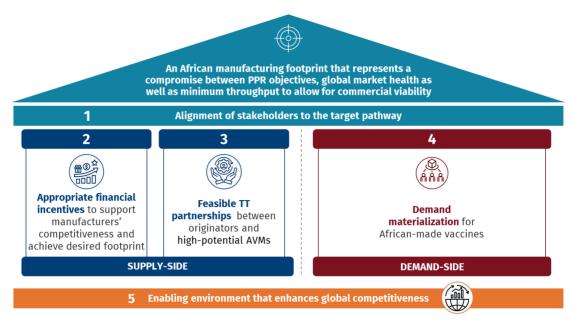
Vaccine manufacturing does not exist in a vacuum and relies on the extensive support of an enabling environment to ensure manufactured vaccines reach the market. The continent currently lacks not only supportive industrial and trade policies, but also skilled workforce and regulatory capacity to achieve this. Regulatory weaknesses in particular may stand in the way of achieving a desirably geographically diversified manufacturer base on the continent. While Egypt and South Africa have attained the capacity to regulate domestic vaccine production (WHO ML3 vaccine producing) for procurement by international organizations such as UNICEF, many African National Regulatory Authorities (NRAs) are yet to achieve the same standard. This limited regulatory maturity on the continent may hinder the approval and oversight processes, potentially slowing down product development and market access, thereby adding another layer of complexity to the use of existing capacity.

As illuminated in this section, the risks of not achieving the target pathway outlined for the African vaccine manufacturing landscape are multifaceted and complex, but not insurmountable. Addressing them requires comprehensive and strategically orchestrated interventions. Recognizing that the endeavour to bolster African vaccine manufacturing presents a unique opportunity; several initiatives are underway by ecosystem stakeholders. In the forthcoming section, we will explore the work already underway and the remaining gaps required to pave the way for a stronger, more resilient African vaccine manufacturing future.

## 4. Interventions to Address Market Risks and Achieve the Target Pathway

To develop a sustainable, fit-for-purpose African vaccine manufacturing footprint, stakeholders across private, public, and social sectors must address the multifaceted market risks already discussed. Here, CHAI outlines a five-part market-shaping intervention strategy, showing how the ecosystem is already collaborating to address these risks, and what gaps remain to support the achievement of the target pathway.

Figure 3: Intervention areas to achieve a fit-for-purpose African vaccine manufacturing footprint.



#### Alignment of Stakeholders to the Target Pathway

To date, stakeholders' involvement with the African vaccine ecosystem has generated significant momentum. However, this has led to some manufacturing projects that are not aligned to public health objectives and which may be unsustainable in the long-term. If stakeholders can align investments and support towards a common target, the chances of achieving a sustainable African vaccine manufacturing footprint can be maximized.

#### Appropriate Financial Incentives to Support Competitiveness

Given the cost disadvantages faced by African manufacturers, financial incentives and risk sharing are necessary to enhance their competitiveness. This will require a blended finance approach, where push funding can reduce the CAPEX burden, provide working capital, and lower the liabilities on manufacturers' balance sheet, while pull funding can create a demand-linked incentive for manufacturers, as they meet specific quality or market access benchmarks.

Significant funding has been put forward to help achieve this. Notably, US\$3.5 - US\$4.5 billion worth of funding announcements have been made through the efforts of many domestic, bilateral, multilateral, and philanthropic investors. The imminent announcement of Gavi's African Vaccine Manufacturing Accelerator (AVMA) promises to provide up to US\$1 billion in pull funding as well. Given the funding commitments already made, the focus now should be on directing it towards the desired outcomes in a coordinated approach across funders. A generally cautious approach to investments into new projects, especially for drug product capacity, would help achieve the target pathway, though some targeted funding to support scale-up of end-to-end capacity and improving capacity utilization of existing manufacturing facilities may be required.

#### Support Feasible Technology Transfer Partnerships

While there is significant drug product capacity on the African continent, too few technology transfer agreements have been signed that can enable actual capacity utilization. It is thus critical to facilitate technology transfer partnerships for antigens that present a viable business opportunity and ensure the build-up of technical expertise and resources where necessary.

The nature of the support required from African vaccine manufacturers will vary significantly based on their unique circumstances, but several specific requests have been heard both from international originators and from African manufacturers. Manufacturers have requested support in aid in due diligence and negotiation processes to establish mutually beneficially collaboration terms, in access to upfront financing to support technology transfers, and, lastly, in technical support to navigate the long and intricate process of technology transfer effectively. The nascent efforts of Africa CDC to support the transfer of vaccine technologies and intellectual property through an enablement unit will assist enormously in this area.<sup>17</sup> But additional support from funders and technical partners to further these activities will be essential to addressing this risk.

#### Demand Materialization for African-Made Vaccines

On the procurement side, a collaborative 'demand commitment' among African governments is pivotal for demand materialization of African-made vaccines.<sup>18</sup> Commitment by governments to prioritize the purchase of African-made vaccines can generate required economies of scale beyond domestic borders. This has been identified as a key action area by both Gavi, in their four-pillar strategy<sup>19</sup>, and Africa CDC in the PAVM Framework for Action<sup>17</sup>.

In the long term this may take the form of the African pooled procurement mechanism, currently being championed by Africa CDC. But even before such a new procurement channel is set up, which is likely to take many years, we can see the importance for countries to preferentially choose African-made vaccines where possible through their current procurement channels in the short-term. This commitment will support the African manufacturers that are first to market and ensure that originators see the benefit of pursuing technology transfers with African manufacturers and establishing manufacturing on the continent.

In implementing such policy measures, neither long-term African pooled procurement nor short-term preferential procurement support, will be enough. While aspiring to support regionalized industries for economic development, budget considerations as well as vaccine affordability and supply security for the population are paramount for both domestic governments and international procurement stakeholders (i.e., Gavi / UNICEF).In addition, the open question remains as to the incentive for non-manufacturing countries to buy African-made vaccines vs. incumbent products as they are not ensured priority during health crises and risk being side lined in future emergencies. A continental policy effort or legal mechanism will need to account for interests of countries with different incentives, and clearly outline current gaps at the domestic level to advance implementation of procurement policy in support of African vaccine manufacturing.

#### **Enabling Environment**

Finally, to facilitate the growth of a successful vaccine industry on the continent, there are several enabling factors that need to be developed. Ongoing regulatory strengthening work from several partners, including the Bill & Melinda Gates Foundation, USAID, and Team Europe, is focused on addressing national regulatory authorities (NRA's) weaknesses. Other projects with regional bodies such as the African Medicines Agency (AMA) and the African Medicines Regulatory Harmonization (AMRH) programme, will also further support manufacturers to seamlessly access the continental market. Ongoing commitment to ensure these activities are successful will be required to ensure that strong continental supply of vaccines is matched by strong regulatory support.

In terms of industrial policy, some African countries have already started changing their policies to ensure the vaccine industry is bolstered at the national level. For example, in Egypt, the government established a Pharma City in the Suez Canal Economic Zone with an offer of zero percent customs and VAT and other non-cash incentives.<sup>20</sup> In Ethiopia similar attractive policies have also been implemented such as the Kilinto Industrial Park

<sup>&</sup>lt;sup>17</sup> PAVM, Framework for Action, March 2022

<sup>&</sup>lt;sup>18</sup> <u>COVAX: Key learnings for future pandemic preparedness and response</u>, Sept 2022

<sup>&</sup>lt;sup>19</sup> Gavi, Expanding sustainable vaccine manufacturing in Africa: Priorities for Support, Nov 2022

<sup>&</sup>lt;sup>20</sup> Suez Canal Economic Zone woos Indian Drug Makers with Incentives, <u>Businessline</u>, December 2020

near Addis Ababa with the aim of attracting pharmaceutical companies.<sup>21</sup> Nevertheless, more concerted efforts are required from country governments to develop supportive industrial policies in Africa to ensure comparable industrial support is offered to African manufacturers as is offered in other parts of the world, such as India.<sup>22</sup>

Sustainable access to low-cost inputs and consumables remains an unaddressed enabling requirement for the vaccine manufacturing ecosystem. A thorough diagnosis of the challenges and identification of potential solutions is required to ensure the success of the African vaccine manufacturing ecosystem, with CEPI and Africa CDC championing these efforts.

## 5. Conclusions

These five interconnected intervention areas create a robust framework for promoting the growth of the African vaccine manufacturing sector. It's vital that this work proceeds rapidly, to capitalize on the current interest and momentum among key stakeholders.

Stakeholders from all sectors are required to advance towards the target pathway and CHAI urges ecosystem stakeholders to take on these challenges to support this strategy for the African vaccine manufacturing ecosystem:

- Funders, donors, and multilaterals can direct funding towards additional drug substance capacity aligned to the target pathway, and redirect support away from new drug product capacity to enhancing capacity utilization of existing drug product capacity.
- African governments can champion demand commitments for African-made vaccines to ensure a sufficient market is available, and support manufacturers with a strong enabling environment through workforce development initiatives, accommodative industrial and trade policies, and regulatory strengthening.
- Private sectors, donors, and multilaterals can provide bilateral technical assistance to manufacturers aligned with the target pathway, in particular, focus on supporting IP holders in targeted technology transfers to Africa by leveraging other access agreements.

We hope that this white paper will serve as a valuable tool within the global health ecosystem, serving as both a catalyst for change and a unifying force to support African vaccine manufacturing. By leveraging its insights, we urge stakeholders to forge collaborative, constructive, and creative partnerships that not only promote global health security and pandemic preparedness, but also ensure the sustainability of antigen markets and the commercial viability of manufacturers.

<sup>&</sup>lt;sup>21</sup> Ethiopia's Chinese-built Industrial Park Attracts World-class Pharmaceutical Firms, Xinhua, May 2019

<sup>&</sup>lt;sup>22</sup> Kamiike, A. (2020). The TRIPS Agreement and the Pharmaceutical Industry in India. Journal of Interdisciplinary Economics, 32(1), 95-113.

#### 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 highquality 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.

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