

Clinton Health Access Initiative, Inc.

The African vaccine manufacturing ecosystem: supply landscape and expansion plans

Vaccine Markets Team
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Key Takeaways

- There are 10 manufacturers with existing vaccine production in Africa, whilst a further 17 additional organizations have publicly announced plans to begin manufacturing on the continent.
- Of the total capacity expansion plans announced (~2.2 billion doses), 85 percent hinge on the manufacture of COVID-19 vaccines, with several manufacturers having announced plans to produce other antigens as well. Given the global oversupply situation for COVID-19 vaccines, CHAI expects a downward correction of these figures as capacity plans mature.
- African manufacturers are becoming more ambitious in terms value chain integration: while the majority of plans state fill and finish as the entry point to vaccine manufacturing, select suppliers plan to include drug substance manufacturing.
- Plans suggest that African manufacturers are looking to leapfrog to next-generation technology platforms which presents opportunities of a strong market position in new antigen markets; however, bears the risks of largely untested vaccines and unestablished markets.
- A long-term commercially viable African vaccine manufacturing ecosystem requires market-shaping to support manufacturers as well as close collaboration across public and private sector stakeholders.

1. Background

The COVID-19 pandemic and the global response to it, has revealed deep inequalities in the current structure of global health institutions and markets. One of the clearest demonstrations of this was the delays experienced by low and lower-middle-income countries (LMICs) in receiving COVID-19 vaccines, particularly in Africa. While some COVID-19 vaccines were made available to lower-income countries early in the pandemic, most early doses went to the wealthiest countries. Many wealthy countries offered citizens third or even fourth booster shots whilst hundreds of millions of people in lower-income countries were still waiting for their first dose.¹

One of the central drivers of this inequality is the lack of vaccine manufacturing capacity on the African continent. Despite having the highest continental incidence of mortality caused by infectious diseases in the world, less than one percent of Africa's vaccine needs are met by products manufactured on the continent.² This meant that when procuring COVID-19 vaccines, African governments often found themselves deprioritized in favor of countries with deeper pockets or domestic production. Whilst the immediate issue of access to COVID-19 vaccines has (broadly speaking) been resolved, the lack of regional vaccine manufacturing capacity remains.

A wave of global momentum and political will amongst local, regional, and global stakeholders has led to the establishment of several efforts to support the scale-up of manufacturing. Most ambitiously, the African Union, through the Partnership for African Vaccine Manufacturing (PAVM) initiative, has announced plans to ensure that 60 percent of all vaccines used on the continent are African-made, supported by a Framework for Action to achieve this ambition.³ In addition, Gavi, which currently accounts for approximately 50 percent of African vaccine procurement by value, is also in the process of potentially updating its market-shaping principles to place

¹ WHO Coronavirus (COVID-19) Dashboard

² John N. Nkengasong, Sofonias K. Tessema, Africa Needs a New Public Health Order to Tackle Infectious Disease Threats, Vol 183 (2), 2020, p296-300, ISSN 0092-8674, <https://doi.org/10.1016/j.cell.2020.09.041>

³ [PAVM, Framework for Action](#), March 2022

a higher value on regional diversification of supply, and to use a targeted financial instrument to support African vaccine manufacturers.⁴

In tandem, there has been an increase in the plans of manufacturers to setup or scale up production, enthusiastically supported by funders. By CHAI's analysis, 17 organizations have plans to begin manufacturing on the continent, and all 10 manufacturers that had some form of vaccine production prior to COVID-19 have relatively advanced plans to scale up production. Sitting behind this is US\$3.5+ billion of announced funding to advance vaccine manufacturing in Africa.⁵

Whilst this burst of attention, energy, and entrepreneurialism is cause for optimism in scaling-up African vaccine manufacturing, it brings with it market concerns as well. For CHAI, two concerns are top of mind. The first concern is that AVM efforts may jeopardize the gains made over the last 20 years in ensuring consistent, low-cost vaccine supply to LMICs. The gains in vaccination rates in LMICs have only been possible due to broad-based price reductions and consistent global supply. However, vaccine markets are fragile due to the intense regulatory scrutiny, tight margins, and long lead times involved in vaccine production. Thus, careful planning will be required to ensure that supporting African vaccine manufacturing does not lead to increased prices and reduced supply security globally. The second concern, heightened by the "start-up" situation in the space, is that uncoordinated partner initiatives result in duplication of efforts, conflicting initiatives, and, ultimately, wasted resources and efforts. To maximize the impact that can be achieved, it is essential to coordinate at the global, regional, country, and manufacturer levels.

In this white paper, we present an analysis of the rapidly evolving African vaccine manufacturing footprint by using publicly available data to identify patterns in the current manufacturing capacity, plans for scale-up, and identify opportunities and challenges facing the African manufacturing footprint as it scales up. This is part of the supply and demand landscaping being undertaken by CHAI to understand market risks and inform a continental market-shaping strategy.

⁴ [Gavi, Expanding sustainable vaccine manufacturing in Africa: Priorities for Support](#), November 2022

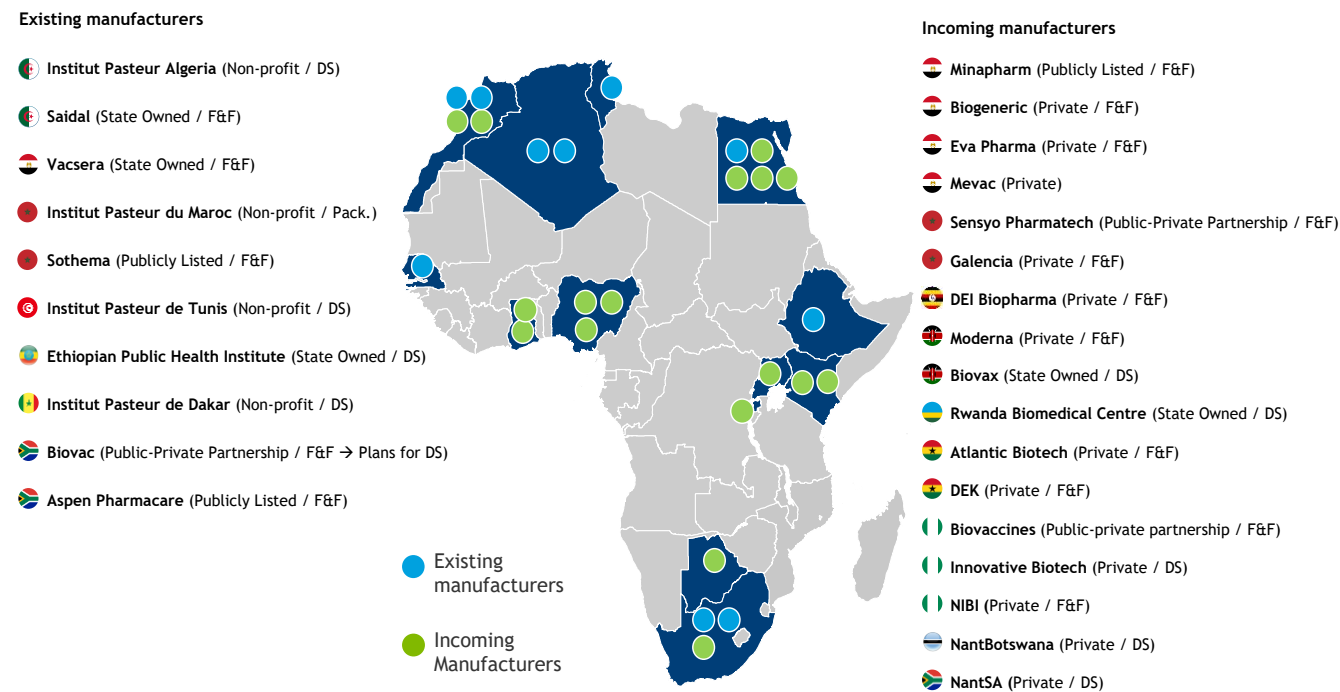
⁵ CHAI Analysis

2. Overview of African Vaccine Manufacturing Footprint and Future Plans

Although the African Union’s 60 percent target for continental vaccine supply is still more than a decade away, ambitious capacity targets and market entry plans have already been announced that, if fulfilled, promise to fundamentally change the vaccine manufacturing ecosystem. The history of commercial vaccine production in Africa dates to 1937,⁶ but to-date has mostly been small scale, focused on fill and finish operations, and concentrated in a handful of countries. With the COVID-19 pandemic, a wave of new market entrants and expansion plans have been announced, particularly focused on the manufacturing of COVID-19 vaccines for the continent. Towards the end of 2022, manufacturers began to consider expanding their portfolios beyond COVID-19 vaccines, and several manufacturing projects across the continent reached solid planning phases.

Geographically, existing vaccine manufacturing capacity on the continent is concentrated in a small number of countries, particularly in North Africa. As can be seen in **Figure 1**, six existing manufacturers and six incoming vaccine manufacturers are headquartered in North Africa, split across four countries (Algeria, Egypt, Morocco, and Tunisia). Based in South Africa, Biovac and Aspen Pharmacare are currently among the most prominent manufacturers on the continent, and both have made significant announcements regarding their plans for vaccine manufacturing, including technology transfers from Korea and India respectively.^{7,8} A further two manufacturers have announced plans to start manufacturing in Southern Africa, in both Botswana and South Africa, as part of the Nant group. The only producer of a vaccine that is currently prequalified by the World Health Organization

Figure 1: Map of current and planned vaccine manufacturing on the African continent, including ownership structure and value chain capabilities



⁶ Institut Pasteur de Dakar

⁷ Biovac Press Release, “Biovac signs deal with IVI to develop and manufacture oral cholera vaccine for African and global markets,” November 2022

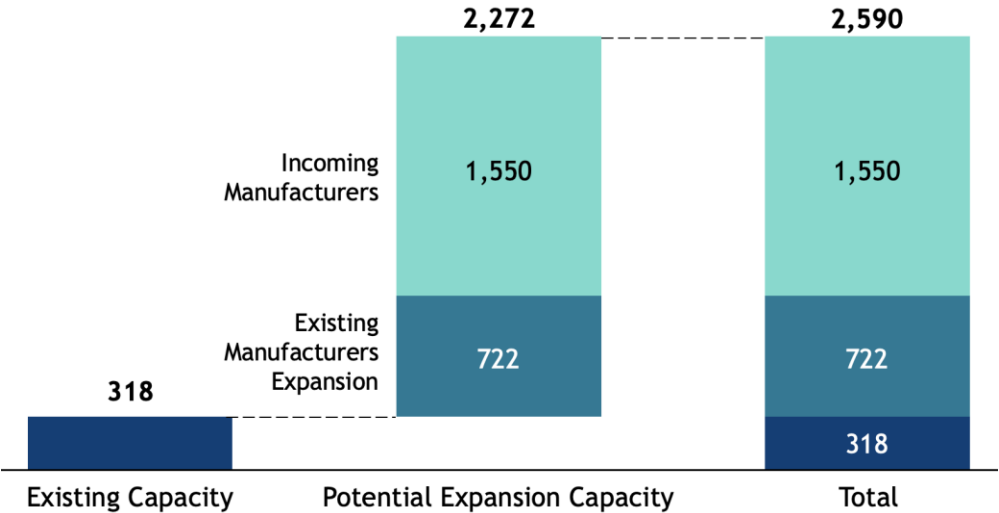
⁸ Aspen Press Release, “Aspen concludes a collaboration agreement to manufacture and make available four Aspen-branded vaccines for Africa,” August 2022

(WHO), making it eligible for UNICEF procurement, is Institut Pasteur de Dakar in Senegal, West Africa. There are a further five manufacturers with plans to start production that are based in West Africa. East Africa has currently the smallest planned footprint, with one manufacturer currently producing vaccines and a further four with announced plans to manufacture.

The plans announced by incoming and existing manufacturers will transform the vaccine manufacturing footprint on the African continent (**Figure 2**). At present, publicly available sources estimate vaccine manufacturing capacity to be around 318 million doses per annum across all stages of the value chain (i.e., including drug substance, fill and finish, and packaging). Approximately 300 million doses (94 percent) of this existing capacity are linked to COVID-19 vaccines produced by four manufacturers (Aspen, Sidal, Sothema, and Vacsera). The remaining 18 million doses are made up of yellow fever, hexavalent, PCV and rabies antigens from various suppliers.

From this low base, the publicly announced scale-up plans would increase the total capacity by 2.2 billion doses per annum. Existing manufacturers have announced plans to add ~722 million doses of capacity and incoming manufacturers have announced plans for a further ~1,550 million doses per annum. A large portion (85 percent) of this announced capacity is currently earmarked for the manufacture of COVID-19 vaccines. However, given the global oversupply situation for COVID-19 vaccines, it is expected that these plans may pivot towards other antigens (or a reduction in planned capacity expansion altogether).

Figure 2: Vaccine Manufacturing Capacity (million doses)

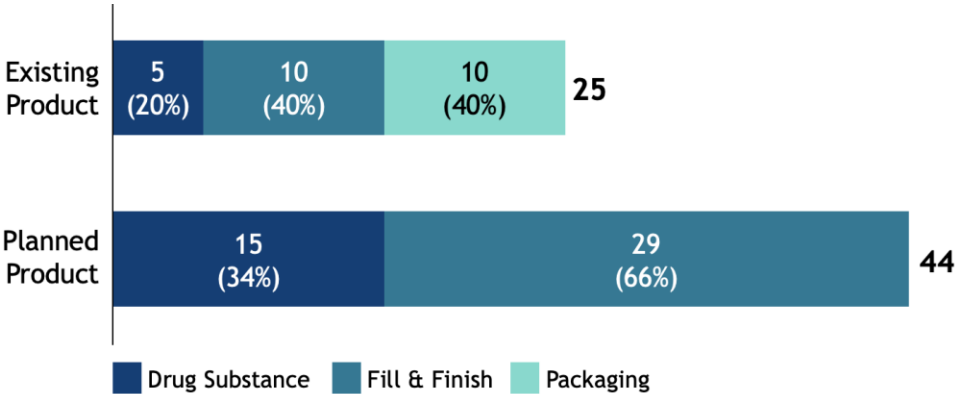


3. Breakdown of Manufacturing Footprint and Future Plans

The COVID-19 pandemic has not only heightened the ambition for African vaccine manufacturing, but it has also led to new types of investors, value chain integration, and increased breadth of portfolio and platform choices. We observe a growing interest from private companies. Whilst amongst existing manufacturers only two (20 percent) are private companies, the overwhelming majority, namely 15 (88 percent) of the incoming manufacturers are structured as private sector organizations, albeit with some public funding in some cases. Where previously African vaccine manufacturing was primarily an interest of state actors, it has now also attracted entrepreneurs looking to transform the market.

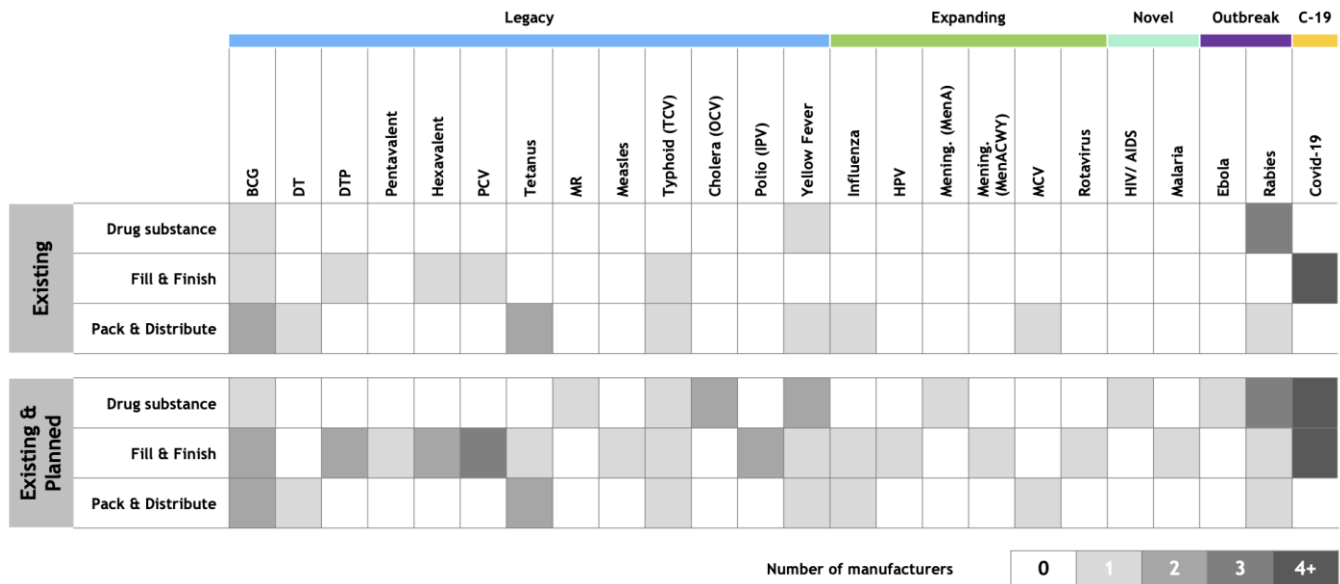
Furthermore, manufacturers have grown more ambitious in terms of the production process they plan to engage in (Figure 3). Whilst only five products (20 percent of the current total) currently contain drug substance (DS) manufactured on the continent, 15 of the 44 announced products will include drug substance manufacturing (34 percent of total plans). If this comes to fruition it would represent a quadrupling of antigens with drug substance manufacturing. The remainder of the manufacturing planned for the continent is currently for fill and finish (FF) (29 products, 66 percent of total plans). Anecdotally, several suppliers have indicated that they intend to progress into drug substance manufacturing through backward integration along the value chain as their manufacturing capabilities evolve.

Figure 3: Value chain integration of current and planned vaccine manufacturing on the African continent



The growth in investment in African vaccine manufacturing has led to a significant expansion of planned vaccine production, spread across multiple antigens in the legacy, expanding, novel, outbreak, and COVID-19 categories (Figure 4). Whilst few overlaps in antigens are identified in the current publicly announced plans by manufacturers, there is a noticeably large number of manufacturers currently focused on the production of COVID-19 vaccines. Given the uncertainty of demand for COVID-19 vaccines in Africa (and the world), this creates a risk for those manufacturers - though these plans may well develop and adapt in line with demand. Further overlaps worth calling out include three manufacturers with plans to fill and finish pneumococcal conjugate vaccines (PCV) as well as two manufacturers respectively with plans to produce drug substance for oral cholera and yellow fever vaccines.

Figure 4: Existing and planned vaccine manufacturing in Africa



These expansion plans are supported by an increase in technology transfers to African manufacturers. The majority of technology transfers announced to date are for COVID-19 vaccines⁹. Transfers for other vaccines include the recently signed agreement between the International Vaccine Institute (IVI), Korea, and Biovac that will see the latter engage in drug substance manufacture of an oral cholera vaccine (OCV)⁷. Similarly, Serum Institute of India (SII) and Aspen Pharmacare have signed a deal for Aspen to manufacture and distribute four vaccines for routine immunization in Africa, namely rotavirus, multivalent meningococcal, hexavalent and pneumococcal vaccines⁸.

Currently, African manufacturers mainly utilize inactivated and live attenuated platforms for vaccine manufacturing. For the future, on the other hand, manufacturers have plans to use next-generation platforms like virus-like particles (VLP) and mRNA platforms. The tilt towards newer platforms by manufacturers mean they could potentially leverage rapid and highly adaptable technology for routine and emerging infectious diseases. Thus, the continent could be better prepared for the next pandemic. Additionally, the use of innovative technologies to produce novel vaccines could allow African vaccine manufacturers to leapfrog existing manufacturers and achieve economies of scale and a strong market position quickly in new markets. However, the use of next-generation platforms like mRNA are largely untested beyond COVID-19 vaccines and the future productivity of these platforms in commercial manufacturing is unknown. As such, there is risk that manufacturers could invest a considerable part of their resources in an ill-defined, oversupplied market.

⁹ Clinton Health Access Initiative, “[A database of local vaccine manufacturing commitments and tech-transfers](#),” June 2022

4. The Way Forward for African Vaccine Manufacturing

Across the vaccine value chain, following the COVID-19 pandemic, the African vaccine manufacturing industry is experiencing a boost in activities. It is crucial to harness and maintain the current interest, momentum, and political will amongst key stakeholders to facilitate the scale-up of fit-for-purpose African vaccine manufacturing. By increasing the volume of high-quality vaccines manufactured in Africa, the global health system can be made more equitable and responsive to African health priorities. Furthermore, Africa and the world can be better prepared for a future pandemic. This objective, however, must be pursued whilst not putting at risk the achievements made over the past years in improving supply security and affordability of vaccines or by supporting manufacturing projects that are not long-term commercially viable and therefore are reliant on continual and extensive external funding.

Despite the funding, plans and interest in vaccine manufacturing in Africa, this will be a long journey. Regulatory systems in Africa are yet to be harmonized and regulatory processes in many countries are slow and opaque. Due to intellectual property restrictions, manufacturers have limited access to tech transfers. Both existing and planned production capacity is still largely focused on fill & finish of drug products, and a lack of established supply chains for inputs and consumables may impact the materialization of even the most realistic plans. Last, but not least, questions of target markets, country preference, and procurement have yet to be answered. To achieve the goal of a long-term commercially viable African vaccine manufacturing sector, realistic planning and coordination across public and private sector stakeholders will be important. CHAI will work to update the information in this white paper as well as its database of technology transfers to African manufacturers at regular intervals as new information becomes available. In a parallel effort, CHAI will continue to engage with global and regional health partners as well as governments to better understand the demand for and future procurement of African-made vaccines. These efforts will contribute to a better understanding of demand- and supply-side market risks and inform fit-for-purpose market-shaping strategies going forwards.

About CHAI

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

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

The CHAI Vaccines Markets Team is supported by the Bill & Melinda Gates Foundation (BMGF) to support vaccine access and pandemic preparedness & response, by working in the African vaccine manufacturing ecosystem, whilst ensuring market health across antigens at a global level and commercial sustainability of manufacturers over time.

CHAI would like to thank the partners and individuals who have contributed to this paper, either by commenting on the draft, reflecting on the data collected, or by sharing their own thought leadership in this field.