

# Localization of Pharmaceutical Manufacturing in Sub- Saharan Africa

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# Table of Contents

1.	Executive Summary .....	4
2.	Background .....	5
3.	Overview of Pharmaceutical manufacturing in Sub-Saharan Africa .....	5
	Market Size .....	6
	Manufacturing Capacity and Geographical Distribution .....	6
	Status of Regulation .....	7
4.	Why local manufacturing? .....	8
5.	Growth Drivers and Market Potential.....	9
	Population Growth and Urbanization .....	9
	Economic Growth .....	9
	Disease Burden .....	9
	Demand for Generic Medicines .....	9
	Government Initiatives and Policy Reforms .....	10
	Market Penetration and Expansion Opportunities .....	10
	Technological Advancements and Innovation .....	10
6.	Challenges Facing Local Pharmaceutical Manufacturing .....	10
	Limited Availability of Human Resources.....	11
	Lack of Good Infrastructure .....	11
	Financial and Technical Constraints .....	11
	Low Government Investment and Incentives.....	11
	Inadequate Policy Implementation and Regulatory Enforcement.....	11
	Corruption and Weak Governance .....	12
	Market and Economic Dynamics.....	12
	Counterfeit Medicines.....	12
	Research and Development (R&D) Limitations .....	13
7.	Proposed Solutions .....	13
	Policy and Regulatory improvement .....	13
	Research and Development (R&D) .....	14
	Pooled Procurement .....	14

	Infrastructure Development .....	15
	Enhancing Workforce Capacity.....	16
	Encouraging Foreign Direct Investment (FDI).....	16
	Stakeholder Collaborations .....	16
8.	Emerging trends .....	16
	Increasing Support from International Stakeholders.....	16
	Policy and Regulatory Frameworks .....	17
	Technology Transfer and Vaccine Manufacturing.....	17
	Digital Transformation in Healthcare .....	17
9.	Conclusion .....	18
	Recommendations.....	18
10.	References.....	21

# 1. Executive Summary

This study explores the current state and potential of local pharmaceutical manufacturing in Sub-Saharan Africa, highlighting the strategic importance of developing a robust pharmaceutical industry to improve health outcomes and enhance economic resilience. Sub-Saharan Africa faces significant health challenges, including a high burden of communicable and non-communicable diseases, a growing population, and limited access to essential medicines. The region relies on imports for over 70% of its pharmaceutical needs, and its healthcare system is further weakened by fragmented supply chains and inadequate infrastructure. The COVID-19 pandemic exposed these vulnerabilities, emphasizing the urgent need to expand local production capacity.

The pharmaceutical sector in Sub-Saharan Africa is underdeveloped, characterized by limited manufacturing capacity and significant geographic disparities. Local production is constrained by various challenges, including weak regulatory frameworks, high compliance costs, and a lack of skilled human resources. Nevertheless, the market is projected to grow from USD 155 billion in 2023 to USD 236 billion by 2030, driven by increasing demand for healthcare services, population growth, and economic development.

Several key drivers influence the growth and potential of local pharmaceutical manufacturing in the region. These include a rapidly growing and urbanizing population, expanding economies with rising incomes, a high prevalence of communicable and non-communicable diseases, government initiatives toward universal healthcare coverage, and technological advancements like digital health solutions, e-pharmacies, and telemedicine. However, growth is hindered by significant barriers such as a scarcity of trained personnel, inadequate infrastructure, high regulatory compliance costs, limited access to capital, low government investment, and fragmented regulatory environments that allow counterfeit medicines to proliferate.

To overcome these challenges, the study recommends several strategies, including harmonizing regulatory frameworks across the continent to facilitate market access, investing in critical infrastructure like reliable power supplies and transportation networks, and attracting foreign direct investment to build local manufacturing capacity. Additionally, it calls for stronger partnerships among governments, private sector entities, and international organizations to align priorities and pool resources, as well as increased investment in research and development (R&D) to foster innovation and reduce dependence on imported active pharmaceutical ingredients (APIs).

The study identifies several emerging positive trends, such as growing international support for building local manufacturing capacity, efforts to create more supportive regulatory environments, and initiatives like WHO-supported technology transfer hubs aimed at enhancing local vaccine production. Ultimately, the study concludes that while there is significant potential for local pharmaceutical manufacturing in Sub-Saharan Africa, realizing this potential requires overcoming substantial challenges. Strategic investments in infrastructure, regulatory reform, workforce development, and collaborative partnerships are essential for building a sustainable and resilient pharmaceutical sector in the region.

## 2. Background

The population of Sub-Saharan Africa is currently estimated to be above 1.4 billion people, which accounts for 17.89% of the global population. The region has one of the highest population growth rates in the world, and the population will continue to grow to at least 2.4 billion (2 times its current size) by 2050.<sup>1</sup>

Africa carries over 20% of the global disease burden.<sup>2</sup> At the end of 2023, the region accounted for 65% of the total of people living with HIV globally.<sup>3</sup> Additionally, the region is heavily impacted by malaria, with over 200 million cases and approximately 500,000 deaths annually, mostly among children under five years old.<sup>4</sup> Also, Sub-Saharan Africa has one of the highest incidences of Tuberculosis (TB), with co-infection with HIV being a significant concern. Further, high incidence of other infectious diseases such as Hepatitis B, and neglected tropical diseases (NTDs), coupled with the growing rate of noncommunicable diseases such as cardiovascular disease (CVD), cancer, diabetes, and chronic respiratory disease have impacted the region, overburdening the already weak healthcare systems.<sup>5</sup>

Most recently, the COVID-19 pandemic revealed the vulnerability of African countries in terms of access and availability of essential medicines. The region significantly relies on imports and donations, with most countries importing more than 70% of health commodities.<sup>6</sup> As a result, the region faced acute delayed access to essential and life-saving medical products during the COVID-19 pandemic. By 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 worlds. This was the same case with the HIV/AIDS and Ebola epidemics despite Africa being hugely affected.<sup>7</sup>

In addition to over-dependence on imports, the regions face supply chain challenges such as poor inventory management systems, inadequate cold chain control, poor infrastructure, and fragmentation. The region also faces workforce capacity-related challenges as well as weak regulatory frameworks.<sup>8</sup> The existing disease burden, inequity, and supply chain vulnerability highlight the need to enhance the local production of pharmaceuticals in Africa to improve availability.

## 3. Overview of Pharmaceutical manufacturing in Sub-Sharan Africa

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<sup>1</sup>Africa Development Bank Group: <https://www.afdb.org/en/knowledge/publications/tracking-africa-progress-in-figures>

<sup>2</sup>Niohuru, I. (2023), Disease Burden and Mortality

<sup>3</sup>WHO- HIV and AIDS- 2024 fact sheet: <https://www.who.int/news-room/fact-sheets/detail/hiv-aids>

<sup>4</sup>WHO: World malaria report 2021

<sup>5</sup>WHO: World health statistics 2019

<sup>6</sup>Steele, Ali, & Levitskiy, (2020) A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic

<sup>7</sup>Sidibé, (2022): Vaccine inequity: Ensuring Africa is not left out

<sup>8</sup>Steele, Ali, & Levitskiy, (2020) A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic

## Market Size

The Africa pharmaceutical market size was estimated at USD 155 billion in 2023 and is projected to reach USD 236 billion by 2030, growing at a compound annual growth rate (CAGR) of 6.12%.<sup>9</sup> The significant market expansion is driven by the rising population and healthcare demands, increasing disease burden, increasing per capita, growth of health insurance schemes, and improving business climate, as well as a shift by local governments towards greater self-sufficiency and reduced dependency on imports.

The pharmaceutical market in Africa is characterized by a dominance of branded medications, which are mainly imported. In 2023, branded medication accounted for 67.2% of the revenue share in Southern Africa and above 70% in East Africa. However, the generic segment is anticipated to witness the fastest growth rate from 2024 to 2030, driven by the expiration of patents and the push for more affordable healthcare options.<sup>10</sup>

In terms of formulation, tablets hold the largest market share compared to other forms such as injectables. Their ease of use, self-administration nature, and affordability make them the preferred choice for consumers. Additionally, the adult segment held the largest share in the pharmaceuticals market in 2023 and is expected to grow rapidly due to the aging population and the rising prevalence of chronic conditions, necessitating ongoing medication management. In terms of diseases, cancer treatment, oncology medications, holds the largest revenue share and is expected to be the fastest growing segment within the focus period.<sup>11</sup>

## Manufacturing Capacity and Geographical Distribution

Pharmaceutical manufacturing in Africa is growing rapidly. However, the industry is unevenly distributed, with a few countries hosting most of the manufacturing plants. As of 2022, there were at least 649 manufacturing plants in Africa with Nigeria leading with 150 plants, followed by South Africa with 122 firms, then Egypt with 120 followed by the next strata – with 30 to 60 plants – composed of Algeria (55), Tunisia (39), Kenya (35), Morocco (33) and Ghana (30).<sup>12</sup> The rest have fewer than 30 plants, with 22 countries lacking production capacity altogether.<sup>13</sup>

In terms of regions, North Africa is leading with the largest share at 272 as well as technology advancements, followed by West Africa, which has 213 plants; southern Africa has 139 plants, and East Africa has at least 60 manufacturing plants with Kenya hosting more than 50% of the plants.

As for vaccine manufacturing, there were only four countries (Egypt, Senegal, South Africa, and Tunisia) with vaccine manufacturing operations in Africa as of 2022. However, more recent data from 2023 indicates existence of 4 additional countries with vaccine manufacturing (Algeria, Ethiopia, Morocco, and Nigeria).

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<sup>9</sup> Grand View Research 2023: <https://www.credenceresearch.com/report/africa-pharmaceutical-market>

<sup>10</sup> Ibid

<sup>11</sup> Ibid

<sup>12</sup> Banda, Mugwagwa, Mackintosh, & Mkwashi (2022). The Localisation of Medical Manufacturing in Africa

<sup>13</sup> Pharmaceutical Market in East Africa: New Avenues Towards Growth by Medic East Africa.

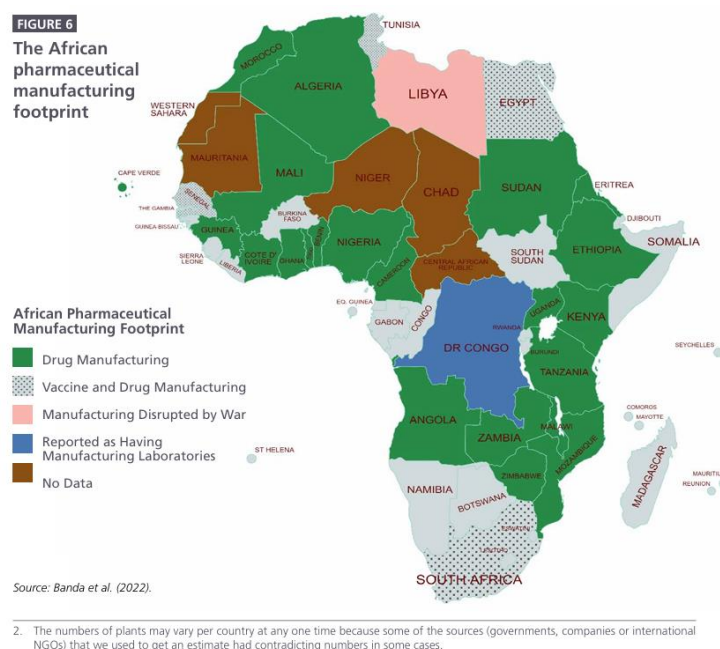
<https://www.medicestafrica.com/2024/pharmaMarket-Report.pdf>

Additionally, nine other countries are planning to acquire new or additional vaccine manufacture capacity including Kenya and Uganda.<sup>14</sup>

There is very limited capacity for manufacturing of raw materials that includes active pharmaceutical ingredients (API) for drugs and active drug substances for vaccines manufacturing. There is some capacity for vaccine active drug substance production in other countries, while for medicines, the entire continent and the world at large is essentially dependent on imported APIs, mainly from China and India. Most sub-Saharan Africa (SSA) countries if not all import 100 per cent of APIs for local pharmaceutical production.<sup>15</sup>

Medical device manufacturing is another neglected sector. More than 90% of medical devices used in public hospitals in the region are imported. There is very limited local production. The figure below shows the footprint of pharmaceutical manufacturing in Africa.<sup>16</sup>

**Figure 1: The African pharmaceutical manufacturing footprint**



Source: Banda et al (2022)

## Status of Regulation

Regulatory capabilities vary across the continent. According to WHO, only 6 countries in Africa have stable, well-functioning and integrated regulatory system is in place, operating at maturity level 3, as of June 2024. These countries are Egypt, Ghana, Nigeria, South Africa, Tanzania, and Zimbabwe. None has the highest level, maturity level 4, which is achieved by a regulatory system operating at an advanced level of performance and

<sup>14</sup> USP 2023: Expanding the capacity to produce vaccines in Africa: Enablers and Barriers

<sup>15</sup> Banda, Mugwagwa, Mackintosh, & Mkwashi (2022). The Localisation of Medical Manufacturing in Africa

<sup>16</sup> Ibid

with continuous improvement. This gap poses challenges in ensuring consistent quality and safety standards across the region.<sup>17</sup>

## 4. Why local manufacturing?

Africa carries over 20% of the global disease burden. The region is heavily impacted by epidemics such as HIV, malaria, and TB, among others. Additionally, infectious disease outbreaks such as Ebola in West Africa coupled with the rise in non-communicable chronic diseases such as diabetes and hypertension has further impacted the region, necessitating the need for a robust and responsive healthcare system. Local pharmaceutical manufacturing can play a crucial role in addressing these challenges by ensuring timely and reliable access to essential medicines tailored to the region's unique health needs.

The COVID-19 pandemic highlighted the vulnerabilities of Africa's healthcare systems, particularly the overreliance on imported medicines and vaccines. The resulting delays and inequities in vaccine distribution underscored the need for self-sufficiency in pharmaceutical production. This realization has spurred renewed political commitments, exemplified by the increased healthcare spending across the continent. In 2020, average general government health expenditure per capita increased by 10% in the region, the largest annual increase on record.<sup>18</sup> Additionally, there is a strong momentum to expand local manufacturing capacities to build a more resilient and independent healthcare infrastructure.

Localizing pharmaceutical manufacturing offers numerous benefits, including reducing dependency on international aid and NGOs, which often subordinate the needs of Sub-Saharan Africa when faced with internal crises. Africa is a continent of great diversity, with significant variations in economic status, GDP, and lifestyle among its many countries and regions. Local production would enable a more tailored healthcare provision, matched to the local socio-economic conditions, leading to more effective and sustainable outcomes.

Local manufacturing of pharmaceuticals can also enhance medicine availability thus reducing the dependency on imports and international donations, which can be unpredictable and subject to delays. Additionally, local production can mitigate supply chain fragility such as preventing quality issues related to shipping and storage, hence ensuring a stable supply of medicines and reducing the risk of shortages. It can also contribute to economic development by creating jobs and stimulating local industries. Additionally, it can enhance affordability due to factors such as incentives resulting in lower production and transportation costs.<sup>19</sup>

In general, local manufacturing can improve resilience, reduce vulnerability to global supply chain disruptions, enhance economic development, and strengthen local health security. Moreover, manufacturers can produce medicines that are specifically tailored to the prevalent diseases and conditions in the region.

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<sup>17</sup> WHO: List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4) as of 13 June 2024

<sup>18</sup> Antoine Lacroix, Cathal Long 'What do we know about health spending in Sub-Saharan Africa?' Accessed 29 June 2024. <https://odi.org/en/insights/what-do-we-know-about-health-spending-in-sub-saharan-africa/>

<sup>19</sup> Steele, Ali, & Levitskiy, (2020) A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic



## 5. Growth Drivers and Market Potential

Africa's pharmaceutical manufacturing sector is poised for substantial growth, driven by a confluence of demographic, disease prevalence, economic, technological and policy factors. The region's expanding population, rising GDP, and increasing urbanization, along with a high disease burden and supportive government initiatives, create a favorable environment for the development of a robust pharmaceutical industry.

### Population Growth and Urbanization

Africa's rapidly expanding population, expected to nearly double by 2050, represents a significant growth driver for the pharmaceutical industry.<sup>20</sup> Additionally, the geriatric population is growing over time as life expectancy increases. This demographic trend, coupled with increasing urbanization, is creating a substantial consumer base with rising healthcare needs.<sup>21</sup> Urban areas offer better healthcare infrastructure, logistics, and greater purchasing power, which accelerates the adoption of modern medicines. The concentration of economic activities in cities further supports the expansion of pharmaceutical markets, as urban households tend to have higher disposable incomes and greater access to healthcare services.<sup>22</sup>

### Economic Growth

Africa's growing GDP and a rising middle class are critical factors in the demand for pharmaceuticals. As disposable incomes increase, more people can afford healthcare services and medicines, including higher-quality branded and generic drugs. This economic upliftment is accompanied by a heightened health consciousness, driving demand for pharmaceuticals to manage both chronic and infectious diseases. The economic growth also attracts more investments in local pharmaceutical manufacturing, creating a positive feedback loop that enhances local production capabilities and market development.

### Disease Burden

The continent faces a dual burden of communicable and non-communicable diseases, including high incidences of infectious diseases.<sup>23</sup> Additionally, changing lifestyles associated with urbanization and economic development is raising the prevalence of lifestyle-related conditions such as obesity, diabetes, and hypertension. This growing disease burden fuels demand for affordable medication.

### Demand for Generic Medicines

The demand for affordable treatments, coupled with the high cost of branded drugs and the expiration of patents, is driving significant growth in the generic drug market. Additionally, there is arising awareness among

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<sup>20</sup>Africa Development Bank Group: <https://www.afdb.org/en/knowledge/publications/tracking-africa-progress-in-figures>

<sup>21</sup>United Nations, (2019) World Urbanization Prospects: The 2018 Revision

<sup>22</sup>Holt, Lahrichi, & Silva, (2015), Africa: A continent of opportunity for pharma and patients

<sup>23</sup> de-Graft Aikins, et al., (2010) Tackling Africa's chronic disease burden: from the local to the global

local healthcare professionals and patients about the comparable efficacy of generic drugs to brand-name counterparts. This has increased confidence and trust in generic products which has seen a surge in generic drug usage, particularly in low- and middle-income countries where cost considerations are paramount. This trend supports the local pharmaceutical industry's growth enabling local manufacturers to produce and supply these essential medicines.<sup>24</sup>

## Government Initiatives and Policy Reforms

Government initiatives, such as the push towards universal healthcare coverage (UHC), play a pivotal role in expanding access to healthcare and pharmaceuticals. Additionally, policy reforms aimed at improving healthcare infrastructure, increasing the number of healthcare professionals, and enhancing the regulatory environment support local drug production. Additionally, governments across Africa have been increasing their healthcare budgets, prioritizing the development of local pharmaceutical industries as a strategy to reduce dependency on imports and enhance greater self-sufficiency.

Additionally, governments in partnership with regional initiatives like the African Medicines Agency are looking into harmonization of regulatory systems across the continent, which can reduce fragmentation, streamline approval processes, and ensure consistent quality standards for medicines produced and sold in Africa. Such regulatory improvements can make the region more attractive for multinational pharmaceutical companies and investors.

## Market Penetration and Expansion Opportunities

The stagnation of pharmaceutical market growth in developed regions necessitates the need for global pharmaceutical companies to seek new markets. Africa's untapped market potential offers significant opportunities for companies looking to establish or expand their presence.

## Technological Advancements and Innovation

Technological advancements, particularly in digital health and telemedicine, are transforming healthcare delivery in Africa. These technologies improve access to healthcare services, especially in remote and underserved areas, and facilitate the efficient management and distribution of pharmaceuticals. The adoption of e-pharmacies and mobile health platforms also enhances the availability of medical products, providing new avenues for pharmaceutical companies to reach consumers.

# 6. Challenges Facing Local Pharmaceutical Manufacturing

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<sup>24</sup>Pharmaceutical Market in East Africa: New Avenues Towards Growth by Medic East Africa.

<https://www.medicestafrica.com/2024/pharmaMarket-Report.pdf>

Pharmaceutical manufacturing in Africa faces numerous challenges that hinder the development and growth of the industry. These challenges include human resources, infrastructure, supply chain, regulatory frameworks, financing, technology, and market conditions.<sup>25</sup>

## Limited Availability of Human Resources

Africa suffers from a scarcity of trained and competent personnel in both the regulatory and manufacturing sectors. This issue is not merely about the lack of education but rather the lack of specific training and practical competence in pharmaceutical manufacturing. The few professionals who are trained often face poor remuneration and working conditions, leading to a "brain drain" where skilled workers seek better opportunities abroad. Additionally, the distribution of healthcare providers is skewed, with most professionals concentrated in urban areas while rural areas, which bear a heavier disease burden, are underserved. This disparity is at times exacerbated by security concerns in rural regions, where fears of violence deter healthcare professionals from working.

## Lack of Good Infrastructure

Inadequate infrastructure is a significant barrier to pharmaceutical manufacturing in Africa. The continent struggles with unreliable transportation systems, poor communication networks, and inconsistent power supplies, all of which are crucial for the efficient operation of pharmaceutical facilities.

## Financial and Technical Constraints

Achieving World Health Organization (WHO) pre-qualification is a significant challenge for manufacturers in the region, primarily due to financial and technical constraints. The high cost of compliance, coupled with the need for specialized equipment, reference materials, and skilled personnel, creates a barrier that many local manufacturers struggle to overcome. Financial constraints are further aggravated by scarce local capital and unfavorable foreign exchange rates, making the importation of necessary materials even more costly.

## Low Government Investment and Incentives

Government investment in the healthcare sector in Africa is generally low. For instance, many countries are yet to meet the Abuja Declaration target of allocating 15% of the government budget to health. There is also a lack of government incentives to promote local pharmaceutical manufacturing. Measures such as tax holidays, funding for research and development, and the establishment of technology incubation centers are either absent or insufficient. This lack of support discourages private investment and innovation in the sector.

## Inadequate Policy Implementation and Regulatory Enforcement

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<sup>25</sup> Ekeigwe, A.A., (2019) Drug manufacturing and access to medicines: Case of West Africa  
Page 11 of 22

The implementation of healthcare policies in Africa is often inconsistent and poorly enforced. For instance, the Primary Health Care (PHC) policy, which aims to ensure equitable access to healthcare, suffers from fragmented services, weak referral systems, and poor infrastructure. Regulatory capacity in the region is also weak, with many National Medicines Regulatory Authorities (NMRAs) lacking the necessary resources and competence to effectively oversee the industry. Additionally, institutional capabilities and strengths of regulatory bodies vary across countries, hampering the growth of the sector. Currently, most medical devices companies in Africa depend on European notified bodies, and this significantly increases their regulatory compliance costs. The porous borders in the region exacerbate the problem by allowing the influx of substandard and falsified medicines.

## Corruption and Weak Governance

Corruption remains a pervasive issue in many African countries, undermining efforts to strengthen the pharmaceutical sector. The Transparency International Corruption Perceptions Index frequently ranks countries in the region among the most corrupt globally. Corruption affects various aspects of the pharmaceutical supply chain, from regulatory approvals to procurement processes, leading to inefficiencies and reduced access to quality medicines.<sup>26</sup>

## Market and Economic Dynamics

The pharmaceutical market in Africa is characterized by fragmented supply chains, high drug prices, and limited access to essential medicines. The inadequacy of medical insurance covers and reliance on out-of-pocket payments place a significant financial burden on individuals. For instance, in the East Africa Community, out-of-pocket expenditure constitutes over 40% of private health spending. Such financial burden on individuals often results in prioritization of basic needs over healthcare expenses.

Furthermore, the dominance of imported medicines, coupled with the limited production capacity of local manufacturers, results in uneven distribution and access of essential medicines, particularly in rural areas. Additionally, local manufacturers rely on imported raw materials which are usually subjected to import duties and value added taxes while imported medicines are often exempt from duties and taxes making the locally produced products expensive compared to the imported ones. High cost of production due to several factors, such as small-scale nature of production, higher unit associated with manufacturing, labor, and utility services, also adds to the high prices. In the case of vaccine manufacturing, the continent's limited capacity for production and the complex logistics required for vaccine distribution further exacerbate these challenges.

## Counterfeit Medicines

The prevalence of counterfeit and substandard medicines is a major concern in Africa. Weak regulatory systems, porous borders, and inadequate enforcement mechanisms allow counterfeit products to infiltrate the market.

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<sup>26</sup> Ibid

These fake medicines not only pose significant health risks to consumers but also undermine trust in the healthcare system and local pharmaceutical products.

## Research and Development (R&D) Limitations

Investment in research and development for pharmaceuticals is very low in Africa. The continent's financial constraints coupled with the limited capacity for upstream research and the absence of strong partnerships between academia, government, and industry stifle innovation. The lack of specialized training and facilities for clinical research further hampers efforts to develop new medicines and treatments.<sup>27</sup>

## 7. Proposed Solutions

The solutions to the challenges facing pharmaceutical manufacturing in Africa require a multi-faceted approach involving government policy and regulatory improvements, industry innovation by investing in R&D and infrastructure, and stakeholder involvement. The relevant details are discussed below.

### Policy and Regulatory improvement

One of the primary solutions to the challenges facing pharmaceutical manufacturing in Africa is government policies and the regulatory environment. The government should balance the need for supporting the growth of the pharmaceutical sector with appropriate taxation policies. While the industry is highly profitable, careful consideration must be given to not overtax it to the detriment of its growth.

Governments should establish fiscal policies that offer tax advantages such as subsidies and tax incentives. This could include reduced import duties on raw materials and machinery, tax holidays for new pharmaceutical ventures, and subsidies for utilities such as electricity and water. These incentives can lower the cost of production and make locally manufactured drugs more competitive compared to imports from countries like India and China. Additionally, establishing special economic zones or pharmaceutical parks with these incentives can attract both local and foreign investment, further boosting the industry. Additionally, investments should be made in infrastructure, including reliable power supply, transportation networks, and industrial parks, which are essential for the smooth operation of pharmaceutical companies.<sup>28</sup>

Protectionist policies, such as import restrictions on finished pharmaceutical products that are also produced locally, can help nurture nascent industries. However, if carried out by many Sub-Saharan African countries the net gains of globalisation may be lost or lessened. Thus, these policies should be carefully designed to avoid stifling competition and innovation. Instead, they should aim to create a balanced environment where local manufacturers can grow and compete globally.<sup>29</sup>

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<sup>27</sup> Steele, Ali, & Levitskiy, (2020) A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic

<sup>28</sup> Ekeigwe, A.A., (2019) Drug manufacturing and access to medicines: Case of West Africa

<sup>29</sup> Gunnella & Quaglietti, (2019) 'The economic implications of rising protectionism: a euro area and global perspective'  
<https://www.ecb.europa.eu/press/economic-bulletin/articles/2019/>.

Improving regulatory frameworks is also crucial for the development of the pharmaceutical sector in Africa. Governments should review and update national policies on medicines to align with international standards. Additionally, there should be a focus on harmonizing regulatory processes across the region, which will facilitate easier access to markets and reduce the cost and complexity of compliance for manufacturers. Moreover, strengthening the capabilities of National Medicines Regulatory Authorities (NMRAs) is essential, including investing in human resources, infrastructure, and quality management systems. Enhanced regulatory oversight will also help in combating the influx of counterfeit and substandard drugs, thereby ensuring that only safe and effective medicines reach consumers.

Security concerns in rural areas, particularly in West Africa, have significantly impacted the distribution of healthcare services and the availability of trained healthcare professionals. Governments should implement robust policies to ensure the safety of healthcare workers and facilities. This includes measures to prevent attacks on healthcare infrastructure, such as improved security protocols and collaboration with local communities and law enforcement agencies.<sup>30</sup>

## Research and Development (R&D)

A significant barrier to the growth of the pharmaceutical industry in Africa is the low level of investment in research and development (R&D).<sup>31</sup> Governments and private sector actors should prioritize R&D investments to foster innovation and the development of new pharmaceutical products. This includes establishing research institutions, providing funding for R&D activities, and creating an enabling environment for clinical trials. Policies should be designed to encourage partnerships between local and international research entities, facilitating technology transfer and capacity building. Additionally, a focus on local production of active pharmaceutical ingredients (APIs) would reduce dependency on imports and strengthen the region's pharmaceutical autonomy.

## Pooled Procurement

Pooled procurement is a formal arrangement where financial and other resources are combined across different purchasing authorities, to create a single entity for procuring health products on behalf of individual purchasing authorities<sup>32</sup>. It is an effective and strategic approach to optimising humanitarian procurement processes, attaining increased cost efficiency and amplifying the impact of organisations across various sectors. Some of the benefits of an effective pooled procurement include cost reduction and negotiation power; quality assurance and standardization; risk mitigation through increased diversification and enhanced resilience; streamlined

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<sup>30</sup> Ekeigwe, A.A., (2019) Drug manufacturing and access to medicines: Case of West Africa

<sup>31</sup> USP 2023: Expanding the capacity to produce vaccines in Africa: Enablers and Barriers

<sup>32</sup> WHO (2021). Pooled procurement: WHO guideline on country pharmaceutical pricing policies. A plain language summary. <https://iris.who.int/bitstream/handle/10665/341901/9789240024670-eng.pdf>

processes through reduced administrative burden; and transparency, equity, and access through inclusive collaboration<sup>33</sup>.

Pooled procurement combines the financial and other resources of purchasing authorities to improve efficiency and create greater purchasing power. Implementing pooled procurement requires an understanding of all the relevant regulatory policies, legal requirements, and financing processes of the participating purchasing authorities. Pooled procurement increases purchasing power because procurement costs are spread over a greater volume and variety of products<sup>34</sup>. It also achieves greater efficiency through the sharing of workload, expertise, and human resources. However, pooled procurement also requires strong political commitment, alignment of legal, regulatory and policy requirements and processes, and the ability to address local needs. Therefore, a successful pooled procurement takes significant will and time to establish. It takes human capacity, skills, and systems but does not necessarily need any physical infrastructure<sup>35</sup>. Pooled procurement can be used to drive overall supply chain transformation and performance.

To compete with imported pharmaceuticals, local manufacturers must focus on improving the cost-effectiveness of their products. Among the key challenges faced by local manufacturers is the dependence on imported API. To mitigate this challenge local manufacturers should adopt pooled procurement mechanism which involves combining resources to create greater purchasing power. This improves efficiency through the sharing of workload, expertise, and cost reduction due to bulk purchases. However, it is important to understand all the relevant regulatory policies, legal requirements and financing processes of the participating purchasing authorities.<sup>36</sup>

## Infrastructure Development

Governments need to invest heavily in infrastructure, including reliable power supplies, good road networks, industrial parks, and communication systems. Infrastructure development is capital-intensive and requires long-term planning, but it is essential for creating a conducive environment for pharmaceutical manufacturing. Incentives like tax holidays, free land leases, and subsidies can attract private investment in these infrastructure projects. Additionally, increasing national budget allocation to healthcare is crucial. This investment can fund the establishment of research facilities, improve healthcare delivery systems, and support local manufacturing initiatives.

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<sup>33</sup> Solvoz. Facilitating Collaborative Pooled Requirement Models. <https://info.solvoz.com/pooled-procurement/>

<sup>34</sup> WHO (2021). Pooled procurement: WHO guideline on country pharmaceutical pricing policies. A plain language summary. <https://iris.who.int/bitstream/handle/10665/341901/9789240024670-eng.pdf>

<sup>35</sup> Barton I., René B. & Malcolm C. (2022). The How of Pooled Procurement an Evaluation of The Positives and Pitfalls in Design and Execution. MSH. <https://msh.org/wp-content/uploads/2022/02/The-How-of-Pooled-Procurement-FINAL.pdf>

<sup>36</sup> Pooled Procurement: WHO guideline on Country Pharmaceutical Pricing Policies 2021

## Enhancing Workforce Capacity

There is a need for dedicated investment in training to build the required range of competencies, capabilities, and skills across the pharmaceutical value chain. This includes leadership training to reduce fragmentation and enhance coordination in the sector.

## Encouraging Foreign Direct Investment (FDI)

Governments should actively promote FDI to support local pharmaceutical enterprises. This can provide access to foreign expertise, technology, and capital, which are crucial for building a robust local pharmaceutical industry.

## Stakeholder Collaborations

Building partnerships between governments and private sector players, including global pharmaceutical companies, is essential. These partnerships can help navigate regulatory environments, align research priorities, and enhance public awareness and healthcare delivery. They can also facilitate the transfer of technology and best practices to local manufacturers.<sup>37</sup>

# 8. Emerging trends

## Increasing Support from International Stakeholders

International support for pharmaceutical manufacturing in Africa has been growing, with key stakeholders providing both technical and financial assistance. A notable initiative is the collaboration between the UN Conference on Trade and Development (UNCTAD) and the East African Community (EAC), which focuses on enhancing essential medicine production capacity and creating sustainable investment frameworks in Ethiopia, Kenya, and Uganda. Also, there is the USAID-funded initiative to support 8 African nations including Uganda, Kenya, and Tanzania, to accelerate HIV/AIDS vaccine development. This funding fosters collaborative efforts aimed at achieving significant breakthroughs in the field.<sup>38</sup>

Additionally, global pharmaceutical companies, including Indian and Chinese multinationals, are increasingly investing in Africa. Chinese firms such as EcoMed Industry, Hangzhou Biotest Biotech, and Hysen (Hangzhou) Biotech are exploring expansion opportunities in Kenya and beyond. Moreover, BioNTech's planned inauguration of Rwanda's first mRNA vaccine factory by 2025 marks a significant milestone in advancing local vaccine manufacturing capabilities. This development underscores a broader trend of international companies

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<sup>37</sup> Holt, Lahrichi, and Santos da Silva (2015) Africa: A continent of opportunity for pharma and patients

<sup>38</sup> Pharmaceutical Market in East Africa: New Avenues Towards Growth by Medic East Africa.

<https://www.medicestafrica.com/2024/pharmaMarket-Report.pdf>



establishing manufacturing bases in Africa to meet local and regional demand, particularly for vaccines and other critical pharmaceuticals.<sup>39</sup>

## Policy and Regulatory Frameworks

There is a concerted effort across the continent to strengthen local pharmaceutical manufacturing through supportive policies and regulatory frameworks. The African Union's 2012 Business Plan for implementing the Pharmaceutical Manufacturing Plan for Africa and the 2nd EAC Pharmaceutical Manufacturing Plan of Action 2017–2027 are key initiatives designed to bolster regional manufacturing capacity. These plans aim to enhance the production capabilities of local firms, enabling them to cater to both domestic and international markets.<sup>40</sup>

Also, there are ongoing regulatory harmonization initiatives. For instance, the African Medicines Regulatory Harmonization Initiative (AMRHI), established in 2009, to promote medicines regulatory cooperation and harmonization in Africa. The initiative focuses on strengthening the technical and administrative capacities of national medicines regulatory authorities to enhance health outcomes in Africa by improving access to safe, effective, and quality medicines.<sup>41</sup> The Pharmaceutical Manufacturing Plan for Africa (PMPA) and the associated GMP Road Map are also crucial, focusing on upgrading local manufacturing facilities to meet international standards and thus ensuring the production of high-quality medicines. Additionally, the endorsement of the African Medicines Agency (AMA) treaty by countries like Rwanda and Kenya signifies a continental commitment to improving medicine regulation and safety standards.<sup>42</sup>

## Technology Transfer and Vaccine Manufacturing

The COVID-19 pandemic has highlighted the need for self-sufficiency in vaccine production, leading to several new initiatives aimed at bolstering local manufacturing capabilities. WHO-supported technology transfer hubs, such as the mRNA hub in South Africa, are critical in transferring knowledge and training to other regions, thus enhancing local vaccine production. These hubs, alongside bilateral agreements, and partnerships with international pharmaceutical companies like Johnson & Johnson and Pfizer, have facilitated the establishment of local manufacturing facilities for COVID-19 vaccines in Africa.

## Digital Transformation in Healthcare

In Africa countries like Libya, Egypt, Morocco, and South Africa are spearheading digital transformation projects within their healthcare sectors. These initiatives include telemedicine, electronic prescribing, and enhanced diagnostic and screening capabilities. Prioritization of these technologies reflects a broader trend

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<sup>39</sup> Ibid

<sup>40</sup> Lartey, P.A., Graham, A.E., Lukulay, P.H. *et al.* Pharmaceutical Sector Development in Africa: Progress to Date. *Pharm Med* 32, 1–11 (2018). <https://doi.org/10.1007/s40290-018-0220-3>

<sup>41</sup> WHO: <https://www.who.int/teams/regulatory-convergence-networks/harmonization>

<sup>42</sup> Pharmaceutical Market in East Africa: New Avenues Towards Growth by Medic East Africa. <https://www.medicestafrica.com/2024/pharmaMarket-Report.pdf>

towards integrating digital solutions in healthcare delivery, which is expected to boost pharmaceutical sales and improve healthcare outcomes in the medium to long term.<sup>43</sup>

## 9. Conclusion

The pharmaceutical manufacturing sector in Africa stands at a crucial crossroads, marked by both immense growth potential and significant challenges. The industry is experiencing rapid expansion, driven by factors such as economic growth, a growing population, increased political commitment, and strategic partnerships. However, the sector faces substantial hurdles, including regulatory fragmentation, infrastructure deficiencies, and insufficient funding. While there are ongoing efforts to harmonize regulations, build local capacity, and enhance technological integration, these challenges require more comprehensive and sustained efforts.

Strategic partnerships will be crucial in overcoming these challenges and ensuring the sector's sustainable development. According to the African Development Bank (AfDB), the continent's pharmaceutical industry will need substantial investment, estimated at up to \$111 billion by 2030, to develop its manufacturing capacity and infrastructure<sup>44</sup>. With continued support and investment, Africa's pharmaceutical industry has the potential to significantly improve healthcare access and contribute to global health security.

## Recommendations

The following recommendations from the review are essential to achieving local pharmaceutical manufacturing:

- 1. Enhance Regulatory Frameworks:** Governments, in collaboration with other stakeholders, should focus on enhancing regulatory frameworks to ensure efficiency and consistency in the pharmaceutical sector. This involves working towards the harmonization of regulatory frameworks across African countries to facilitate the movement of pharmaceuticals and improve regulatory efficiency. Strengthening National Medicines Regulatory Authorities (NMRAs) by enhancing their capacity through training, funding, and resource allocation is crucial. Additionally, it is essential to ensure all existing regulatory frameworks are up-to-date and strictly enforced to help fight against counterfeit, expired, and substandard drugs, and ensure credibility.
- 2. Develop Comprehensive Government Investment Plans:** Countries should create comprehensive government investment plans focusing on critical infrastructure and resources to support pharmaceutical manufacturing. These plans should include investments in reliable power supplies, communication networks, transportation networks, industrial parks, research and development (R&D), and workforce development. Setting clear targets and annual progress benchmarks for accountability is vital, involving all relevant stakeholders to monitor and evaluate progress effectively.
- 3. Foster Collaborations among Stakeholders:** Governments should continue to foster partnerships with various stakeholders, including the private sector, supranational organizations e.g., UN, WHO, local and international manufacturers, and others. These partnerships can secure funding and capacity-

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<sup>43</sup> Africa's next chapter: a continent of opportunities

<https://www.iqvia.com/blogs/2023/09/africas-next-chapter-a-continent-of-opportunity>

<sup>44</sup> African Development Bank Group AfDB, (2022) A New Frontier for African Pharmaceutical Manufacturing Industry

building support, essential for the industry's growth. Promoting the transfer of technology and joint research and development initiatives through these partnerships will also enhance the sector's capabilities and innovation potential.

4. **Create Enabling Environment:** African governmental agencies should encourage regional integration and trade agreements to facilitate pooled procurement and shared access to raw materials and active pharmaceutical ingredients (APIs). Enhanced regional cooperation can create a more efficient and cost-effective supply chain, benefiting all participating countries. Additionally, governments should implement policies that support local pharmaceutical manufacturers and make locally produced drugs cost competitive. Providing tax incentives, subsidies, and other fiscal policies can help achieve this, along with protectionist measures where necessary to safeguard local manufacturers.
5. **Ensure Healthcare Worker and Infrastructure Security:** To maintain a stable and secure health supply chains, governments should establish policies to prevent attacks on healthcare workers and infrastructure. Implementing stringent legal measures, such as long sentences for those who attack or damage any part of the health supply chain, can act as a deterrent and protect essential healthcare services.
6. **Establish Regional Pharma Manufacturing Hubs:** All stakeholders should collaboratively work towards establishing regional pharmaceutical manufacturing hubs in Eastern, Western, Central, and Southern African regions. These hubs can expand drug availability, lower production costs, and achieve economies of scale for long-term sustainability. These hubs could begin with pharmaceutical commodities such as tablets, capsules and general antibiotics with emphasis on importation of APIs<sup>45</sup>.
7. **Allocate Budgets for Research and Development:** Countries should ensure a significant proportion of government budgets is allocated to wider research and development in the healthcare sector to sustain innovation. This can boost the sector's competitiveness and ability to respond to unexpected challenges. Additionally, multinational corporations should be encouraged to support research and development, capacity development and technology transfer, contributing to the growth of local pharmaceutical manufacturing capabilities.
8. **Promote Foreign Direct Investment (FDI)** to enhance access to raw materials, technical expertise, and technology. Governments should create an enabling environment to attract and retain such investments, further bolstering the sector's development and sustainability.



## 10. References

- African Development Bank Group AfDB. (2022). *A New Frontier for African Pharmaceutical Manufacturing Industry*.
- Awuor, E., & Amponsah, P. (2023). *Local Manufacture of Pharmaceutical Commodities in Sub-Saharan Africa: An Empirical Literature Review*. doi:<https://doi.org/10.47772/IJRISS.2023.70539>
- Banda, G., Mugwagwa, J., Mackintosh, M., & Mkwashi, A. (2022). *The Localisation of Medical Manufacturing in Africa*. *IEJ Research Reports; Institute for*. The Open University. Retrieved from <https://oro.open.ac.uk/87114/>
- de-Graft Aikins, A., Unwin, N., Agyemang, C., Allotey, P., Campbell, C., & Arhinful, D. (2010). *Tackling Africa's chronic disease burden: from the local to the global*. *BMC: Globalization and Health*. doi:<https://doi.org/10.1186/1744-8603-6-5>
- Ekeigwe, A. A. (2019). *Drug manufacturing and access to*. Lagos. doi:<https://doi.org/10.1186/s41120-019-0032-x>
- Grand View Research. (2023). *Africa Pharmaceutical Market Analysis 2018-2030*.
- Gunnella, V., & Quaglietti, L. (2019, 3). The economic implications of rising protectionism: a euro area and global perspective. *ECB Economic Bulletin*. Retrieved August 06, 2024, from [https://www.ecb.europa.eu/press/economic-bulletin/articles/2019/html/ecb.ebart201903\\_01~e589a502e5.en.html](https://www.ecb.europa.eu/press/economic-bulletin/articles/2019/html/ecb.ebart201903_01~e589a502e5.en.html)
- Holt, T., Lahrichi, M., & Silva, J. S. (2015). Africa: A continent of opportunity for pharma and patients. *Mckinsey*. Retrieved from <https://www.mckinsey.com/industries/life-sciences/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients>
- Lacroix, A., & Long, C. (2024). What do we know about health spending in sub-Saharan Africa? *ODI*. Retrieved from <https://odi.org/en/insights/what-do-we-know-about-health-spending-in-sub-saharan-africa/>
- Mackintosh, M., Mugwagwa, J., & Geoffrey Banda. (2017). *Local production of Pharmaceuticals and health system strengthening in Africa*. Federal Ministry for Economic Cooperation and Development (BMZ).
- Medic East Africa co-located with Medlab East Africa. (2024). *Pharmaceutical Market in East Africa: New Avenues Towards Growth*.
- Niohuru, I. (2023). Disease Burden and Mortality. In Niohuru, *Healthcare and Disease Burden in Africa* (p. 35). Springer, Cham. doi:[https://doi.org/10.1007/978-3-031-19719-2\\_3](https://doi.org/10.1007/978-3-031-19719-2_3)
- Rickwood, S., & Lutzmayer, S. (2023, September 22). *Blogs: Africa's next chapter: a continent of opportunity*. Retrieved from IQVIA: <https://www.iqvia.com/blogs/2023/09/africas-next-chapter-a-continent-of-opportunity#:~:text=The%20African%20pharmaceuticals%20market%20E2%80%93%20excluding,global%20forecast%20growth%20rates7>
- Sidibé, M. (2022, January 24). *Articles*. Retrieved from Brookings: <https://www.brookings.edu/articles/vaccine-inequity-ensuring-africa-is-not-left-out/#>

- Steele, P., Ali, D. G., & Levitskiy, A. (2020). *A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic*.
- United Nations. (2019). *World Urbanization Prospects: The 2018 Revision*. New York.
- United Nations Industrial Development Organization (UNIDO). (2019). *Pharmaceutical Industry in Sub-Saharan Africa: A Guide for Promoting Pharmaceutical Production in Africa*.
- USP. (2023). *Expanding the capacity to produce vaccines in Africa: Enablers and Barriers*.
- WHO. (2019). *World Health Statistics 2019: Monitoring Health for the SDGs, sustainable development goals*.
- WHO. (2021). *Pooled procurement: WHO guideline on country pharmaceutical pricing policies. A plain language summary*. Retrieved 08 06, 2024, from <https://iris.who.int/bitstream/handle/10665/341901/9789240024670-eng.pdf#:~:text=Pooled%20procurement%20is%20a%20formal%20arrangement%20where%20financial,health%20products%20on%20behalf%20of%20individual%20purchasing%20authorities>.
- WHO. (2021). *World Malaria Report*. Geneva: World Health Organization.
- WHO. (2023). *Country Disease Outlook*.
- WHO. (2024, July 22). *Fact Sheet- HIV and AIDS*. Retrieved from World Health Organization: [https://www.who.int/news-room/fact-sheets/detail/hiv-aids?gad\\_source=1&gclid=Cj0KCQjwwae1BhC\\_ARIsAK4JfrwGZJm-AG0-MIBpA26rRt9aDhpijolMg9cbUAaJUNWs\\_aQtvQwb-GIaAkliEALw\\_wcB](https://www.who.int/news-room/fact-sheets/detail/hiv-aids?gad_source=1&gclid=Cj0KCQjwwae1BhC_ARIsAK4JfrwGZJm-AG0-MIBpA26rRt9aDhpijolMg9cbUAaJUNWs_aQtvQwb-GIaAkliEALw_wcB)
- WHO. (2024). *List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4) (as benchmarked against WHO Global Benchmarking Tool (GBT) (in alphabetical order)*. WHO. Retrieved August 06/08/2024, 2024, from <https://www.who.int/publications/m/item/list-of-nras-operating-at-ml3-and-ml4>
- World Health Organization. (2017). *Leave no one behind: strengthening health systems for UHC and the SDGs in Africa*. Cité du Djoué, Brazzaville, Republic of Congo. Retrieved from <https://iris.who.int/bitstream/handle/10665/259686/9789290233893-eng.pdf?sequence=1&isAllowed=y>
- World Health Organization. (2019). *A Heavy Burden: The Indirect Cost of Illness in Africa*. Praia, Cabo Verde,. Retrieved from <https://www.afro.who.int/news/diseases-cost-african-region-24-trillion-year-says-who>