

# Challenges and Opportunities in the African Pharmaceutical Industry

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## Abstract

**Background:** The pharmaceutical industry in Africa has significant potential for growth; however, it is overwhelmed with grappling challenges. Nonetheless, these challenges can create a window of opportunities for innovation. This article provides an in-depth analysis of the profound challenges and opportunities in the continent's pharmaceutical industry. **Methods:** Using data collected from published literature, reports and gray literature was used to conduct a narrative review. Using data collected from various publications related to the subject matter in African countries and other countries facing similar challenges in relation to drug manufacturing and access to essential medicines. **Results:** The high burden of both communicable and non-communicable diseases create the need for increased production of medicines against the limited and incapacitated number of pharmaceutical industries available within the region. A number of challenges affecting the pharma sector growth in Africa includes, fewer pharmaceutical companies, exorbitant prices of raw materials, foreign dependence on importation of pharmaceutical products, increase counterfeit/falsified products on the market, poor investment into the pharmaceutical sector, research and development by government, shortage of skilled labor, poor infrastructure poor manufacturing conditions, regulatory challenges, limited technological advancement among others. **Conclusion:** This article reifies that the African pharma sector is faced with numerous challenges that also provides unique opportunities for growth and innovation in the region.

**Keywords:** Africa, pharmaceutical, manufacturing, challenges, opportunities

## INTRODUCTION

By 2025 and beyond the African pharmaceutical market is expected to exceed \$60 billion with the population of over 1.4 billion people [1]. The continent's pharmaceutical industry has been identified as a key player in the industrialization and revolution of the continent by developing self-reliant and competitive drug manufacturing industries and to ensure better access to medicines in the region. Thereby fostering economic growth, reducing dependency on imports, and promoting healthcare sustainability across Africa [2].

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Received date: September 27, 2024

Accepted date: October 07, 2024

Published date: November 04, 2024

**Citation:** Petty Miyanda, Dalitso Zgambo. Challenges and Opportunities in the African Pharmaceutical Industry. Research & Reviews: A Journal of Pharmaceutical Science. 2024; 15(3): 88–98.

Despite this potential only 3% of the medicines consumed in the continent are locally produced in a few regions. There are only roughly 375 drug-producing industries, mostly in the northern region [3]. Those in sub-Saharan Africa are clustered in nine out of 46 countries [3], and these account for essential medicines against the (25%) world disease burden that Africa faces [4]. The pharmaceutical production in Africa is yet to reach its required capacity to meet the massive demands of medicines and health products. Over 75% of medicines and active pharmaceutical ingredients (APIs) are imports, this overdependence on

foreign imports, gaps in regulatory policies and harmonization creates a limiting atmosphere for manufacturers in Africa leading to stunted growth of local pharmaceutical production [5]. Furthermore, challenges, such as inadequate infrastructure, limited access to financing, and a shortage of skilled workforce exacerbate these issues, hindering the continent's ability to build a robust and competitive pharmaceutical industry capable of addressing the healthcare needs of its population [6]. As a result of these challenges, the African pharma industry is exposed to vulnerabilities, such as currency fluctuations and supply chain disruptions that can cause unavailability or unaffordable essential medicines.

The southern part of Africa depends mainly on foreign import of pharmaceutical products and raw materials for drug manufacturing [7, 8]. If the health targets of Agenda 2030 and Agenda 2063 is to be achieved for Africa aimed at addressing the increasing numbers of both communicable and non-communicable diseases, ending of HIV/AIDS, TB, and malaria by 2030 [9]. There is pertinent need to develop strategies that will strengthen Africa's capacity to manufacture medicines of high quality and cost effective for sustenance and economic growth of the continent [10].

### **Challenges and Opportunities in Africa's Pharmaceutical Sector**

There are numerous challenges that impede the African pharmaceutical industry's growth and capacity to meet the demand for drug production and better health outcomes for the continent.

#### **Limited Local Production**

The inadequacy in local pharmaceutical production in the continent is a critical challenge that is associated with numerous factors, including high cost of raw materials. With approximately 375 drug-producing industries. This is massively pale in comparison with China and India where 10,000 and 5000 drug manufacturers, respectively, serve 1.1 billion people [3]. This limitation is associated with numerous factors including lack of investment in pharma sector, inadequate infrastructure and a shortage of skilled labor (skills gap). Therefore, this creates an overdependency on foreign imports of pharmaceutical products causing serious repercussions. Mostly during global crises, such as the previous COVID-19 pandemic that cause world-wide travel bans and lockdowns which have an impact on drug manufacturing capacity and importation [11–13], spawning medicine shortages across the continent. This can potentially engender increased circulation of counterfeit/falsified medicines. These disruptions highlight the urgent need for Africa to strengthen its pharmaceutical supply chains and reduce reliance on external sources to ensure uninterrupted access to essential medicines during emergencies [14]. Building resilient local manufacturing capabilities and enhancing regional cooperation are critical to mitigating the risks associated with global supply chain disruptions and safeguarding public health across the continent. Increased local pharmaceutical manufacturing is imperative to ensure continued access to effective, quality and affordable medicines [15]. High dependency on foreign medicines and raw materials (APIs and excipients), limited skilled labor in the continent, lack of regulatory harmonization, unenabling conditions for local manufacturers are all among the many challenges affecting the industry [16].

These challenges expose the continent to significant vulnerabilities, including disruptions in supply chains and currency fluctuations, which can render essential medications either unaffordable or entirely unavailable. Such vulnerabilities undermine public health and exacerbate existing inequalities [17]. Thus, the need to develop comprehensive strategies focused at building Africa's capacity to independently manufacture affordable and high quality pharmaceuticals. By building local manufacturing capacity, improving regulatory frameworks, and fostering innovation, the continent can not only enhance its healthcare outcomes but also stimulate and sustain industrial and economic growth. This strategic focus will reduce dependency on external sources, stabilize medicine prices, and create a more resilient and self-reliant pharmaceutical industry, ultimately contributing to long-term prosperity and wellbeing across Africa [18].

With approximately 375 drug-producing companies and the majority concentrated in the northern region of Africa limited local production is expected to increase, compared to India and China where 5000 and 10,000 drug manufacturers, serve 1.1 billion people, respectively [3]. The exorbitant cost of raw materials is among the many contributing factors to the dearth of pharmaceutical manufacturing industries in the continent.

The availability of raw materials (APIs and general excipients) and equipment determine the cost of production and quality of manufactured drugs. Pharma companies in Africa incur a high cost of drug production as mostly all needed equipment and raw materials are imported. This severely affects the quality and quantity of medicines produced with stunted profit margins that deter both local and foreign investment and hampers the growth sector [19]. The World Bank in 2005 identified Kenya, Nigeria, South Africa, and Zimbabwe to possess the industrial potential that can be siphoned into production of drugs for local and export purposes. However, there was a concern that this capacity was prone to deplete provided the economic cost of local pharma production remains high or if the quality of produced drugs is substandard [20]. Paucity of support infrastructures, such as constant power supply, communication networks, and transportation systems in most of Africa's resource limited members associated with their weak economy and excruciating poverty levels are constraints to local production and growth of the pharma sector [21, 22].

### **Overreliance on Foreign Imports**

About 7%–90% of pharmaceutical products including APIs in the continent are imported [3]. This inordinate reliance on imports predisposes Africa to drug shortages. In essence, this shortage emanates from two focal reasons: fewer numbers of drug manufacturing companies in individual countries across Africa especially the sub-Sahara. Additionally, there is massive cynicism associated with locally produced (in country) pharmaceutical products, causing for substantial use and demand for foreign pharmaceutical products.

This excessive demand for foreign products is unparalleled to importable quantities causing reduced access to medicines and poor health outcomes. To this effect, production and circulation of counterfeit products often marketed as original drugs to oblivious end users [23].

Overdependence on foreign imports also influences political and economic power of African countries with inflation, reduced currency values and increased interest rates causing international trade deficits [24]. Overdependence on foreign imports also influences political and economic strength of African countries. This leads to inflation, reduced currency values and increased interest rates causing international trade deficits [24]. This is against the substantial taxation imposed against pharmaceutical industries, insufficient financial leverage for manufacturers, and a lack of government incentives that promote local research and development in medicine [25].

Establishing effective pharmaceutical drug policies since most of the medicines used in Africa are imported; drug policies that target the improvement of local production of drugs would greatly improve the access to medicines in the region [26].

Historically, poor implementation of existing policies has led to a shortage of essential medicines and will continue to do so unless deliberate interventions are made. Such interventions should include strengthening the drug policies to support local expertise in the manufacture and quality control of drugs [26]. Adequate training and funding of drug regulatory agencies in the region should be put in place as they are critical to eliminating the distribution of fake and counterfeited medicines. Collaboration between countries in the region to develop a system to limit the free movement of fake and adulterated drugs would help to support local manufacturers [27]. Equally essential to this collaboration is the implementation of a strong regulation and enforcement mechanism to ensure strict adherence to these policies. Smooth development and enforcement of drug policies have the potential to bring the continent one step closer to achieving access to safe and quality medicines. In addition,

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harmonization of African Medicines Agencies is also a very important step to address the anaemic access to medicines on the continent [28]. All in all to there is need to invest more in ensuring increase in the presence of more pharmaceutical companies. Private and public partnerships in this regards would be beneficial. Additionally, enhancing the presence of the proposed AMA across Africa is cardinal [29].

### **Unfavorable Manufacturing Conditions**

Manufacturing plants of low capacity and output are used for drug production in Africa [29,30]. They lack the required manufacturing equipment with operations that barely meet international standards [3]. The low output capacity limits the cost competitive advantage of local manufacturers to the foreign ones. Pertaining to the production solid dosage forms, a study by McKinsey highlighted the need for African industries to produce about half a billion tablets annually to attain effective cost competitiveness with India this is a country with more than 10 times the number of industries compared to Africa as a continent [3]. High electricity costs, massive power supply interruptions that have are being exacerbated by poor rainfall patterns due to climate changes (hydroelectricity) and poor transportation systems have further affected the utilization and efficiency of production plants. This is addition to the pre-existing challenge of fewer plants across the continent. This low manufacturing capacity has oftentimes lead to exorbitant drug prices which discourages local manufacturers [31]. Patent challenges and limited investment in research and development have created a barrier for local manufacturers and researchers in producing new medicines and usage of novel equipment and techniques [32]. Reports have shown fewer numbers of researches are conducted in Africa these of which are not put to practice [30]. Poor funding and investment incentives by governments in Africa has caused a deficiency research collaboration within the continent, ultimately affecting production of new drugs [33].

Investment focused on making the continent conducive for pharmaceutical manufacturing is important towards attracting more international investors and massive investment in pharmaceutical research. This includes establishing more in-continent pharmaceutical companies. Currently, there is growing interest among African and international policymakers, researchers, as well as some donors and suppliers, to grow the local pharmaceutical supply by supporting both new and existing companies on the continent.

This is much-needed to improve the continent's capacity to produce medicines for its populace. Investing in establishing more in continent pharmaceutical companies will improve access to medicines which is crucial to attain universal health coverage in Africa [34].

There is a growing need to invest in herbal medicine research in Africa. However, the on-going struggle to protect patents persists and poor advocacy action is still growing in this regard. Initiative should be established to protect African-based patents. Overall, limited operational capacity of pharmaceutical industries coupled with excessive costs of raw materials in the African pharmaceutical industry can be tackled in a number of ways [35].

Firstly there is need for re-orientation of National Medicines Regulatory Medicines Authorities (NMRAs) focus to expanding and strengthening already existing pharmaceutical industries rather than focusing on regulation of medical products [36]. Further recommendations include: African Medicines Agency (AMA) should establish additional pharmaceutical companies. African governments should subsidize raw materials, including APIs. Enhanced Research on cost-effective and readily available raw materials. Provision of government grants to local manufacturers [37].

### **Shortage of Skilled Labor**

A persistent skills gap threatens to hamper the growth and potential of pharmaceutical production in Africa [38]. Moreover, shortage of skilled labor affects various sectors in the industry including, manufacturing, research and development, quality assurance supply chain management and regulatory affairs. Hence, understanding the depths of the skills shortage, its causes, impacts, and, most

importantly, the strategies required to bridge this gap is fundamental [39]. Recent studies and reports have highlighted the magnitude of this challenge. There is a deficit in knowledge and expertise associated with pharmaceutical research, the operation of advanced industrial tools and machinery necessary for boosting local drug production [40].

According to the African Union (AU), a significant increase in skilled professionals is required in the continent's pharmaceutical sector to meet the projected demand by 2030 [18, 35]. The World Health Organization (WHO) has equally emphasized the critical shortage of healthcare professionals, including those in the pharmaceutical sector, with an estimation of reaching 6.1 million by 2030 [35].

### **Causes of the Skills Gap**

Several factors can be attributed to the skills shortage in Africa's pharmaceutical industry. A few of them are:

#### ***Poor Collaboration Between the Pharma Industry and Academia***

There is a significant mismatch between the curriculum offered by higher educational institutions and the actual skills required in the pharmaceutical industry creating educational shortcomings [40]. Additionally, inadequate availability of laboratory equipment in learning institutions with lack of laboratory reagents for conducting pharmaceutical experiments in basic pharmaceutical technology. Furthermore, there is lack of specialized programs focusing on pharmaceutical sciences and related fields [41].

Despite pharmacy (pharmaceutical science) being one of the popular courses in both private and public medical universities, experts from the industry are rarely involved in curriculum or course planning consultation by faculties. Similar observations were reported in Bangladesh involving chemistry and engineering courses [42]. This has exacerbated the gap between labor supply and industry demands. The low expectations from graduates and increased emphasis on on-job training by stakeholders can be accounted for by the lack of linkage between academia and the industry. Reports have shown that industry stakeholders are interested in collaborating with academia sector and governments in designing and updating the curriculum for pharmaceutical sciences and related fields [43].

#### ***Limited Exposure to Industry Standards***

Many African-trained professionals lack exposure to global pharmaceutical practices and standards and consequently their ability to compete on an international level [44].

#### ***Inadequate Investment in Training and Development***

There's a general underinvestment in continuous professional development and training within pharmaceutical companies, limiting the growth and adaptability of the workforce [45].

#### ***Brain Drain***

The migration of skilled professionals in search of better opportunities outside the continent further exacerbates the skills shortage by hampering research and development in the continent [46].

## **IMPACT OF THE SKILLED WORKFORCE SHORTAGE**

### **Innovation Crisis**

Being a knowledge and research-based business. The competitiveness of the pharmaceutical industry relies on the innovative research and development efficiency. With Africa's deficits in education, insubstantial exposure to global standards of the pharmaceutical industry, appalling investment practices in research and development, lack of skilled workforce due to the brain drain and poor education. Africa's pharma industry will continue to lag in innovation and development of new products [47].

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**Regulatory Challenges**

The lack of skilled professionals in regulatory affairs slows down the approval process for new drugs and compliance with international standards [74].

**Manufacturing Inefficiencies**

The shortage of skilled manufacturing personnel affects the quality and quantity of locally produced pharmaceuticals [48].

**Poor Supply Chain Management**

Lack of expertise and corruption in supply chain management can cause inefficiencies and higher production costs [49].

**APPROACHES TO BRIDGING THE SKILLS GAP****Strengthening Educational Infrastructure*****Curriculum Overhaul***

It is imperative for academic training institutions to modernize their curriculum and course planning activities to tailor to both current and future needs of the pharma industry. This can be achieved by incorporating practical skills and enhanced exposure to the pharmaceutical industry. Additionally, working hand-in-hand with industry insiders in updating curriculums and course planning will ensure production of a skilled workforce for technical occupations. Such policy measures would be essential [42].

**Specialized Training Programs**

Establishing specialized training centres and programs focusing on pharmaceutical sciences, biotechnology, and related fields is crucial.

Governments in the continent should consider investing into pharmaceutical industry specialized training institutes, such as the already existing technical and vocational education and training (TEVET) institutes to provide the needful training in both theoretical and practical aspects regarding pharmaceutical manufacturing, production and management to Africans. There will enable retention and growth of knowledge within the region and overcome brain drain challenge, further it offers opportunities for collaboration with the pharmaceutical sector [43]. Such specialized training institutes can meet the gap in research and development of new drugs in the continent. The deficiency in quality research and development in the continent is partly attributed to the narrow production and supply of enabled researchers and scientists. The labor force does not match the enthusiasm of stakeholders in research and development [44].

**PHARMACEUTICAL INDUSTRY – ACADEMIA COLLABORATION****Internships and Apprenticeships**

Reports have consistently found that there is poor linkage between academia and the pharmaceutical industry. Partnerships between the industry and academic institutions to offer practical training opportunities can curb the gap between theoretical knowledge and practical skills. Pharmaceutical enterprise associations can undertake the leading role in collaborating with departments of pharmacy, microbiology, chemistry, and engineering in both private and public universities to reconcile their curriculum so ensure that graduates acquire practical understanding of the pharma sector during undergraduate training [45]. Launching of hands on training programs, periodic workshops, internships programs, and conferences by pharmaceutical associations and training institutions in association with industry insiders can be useful in provision of much needed exposure to graduates on industry dynamics. Furthermore, a trio-collaboration would be useful among policymakers, industry and academia experts for this to be fruitful [46].

### **Continuing Professional Development Training**

With an exponential rise in pharmaceutical innovations from formulation devices, equipment and production techniques. it is pertinent for pharmaceutical companies in Africa to invest in periodic continued training programs for their existing workforce to enhance professional skills [47].

## **POLICY INTERVENTIONS**

### **Government Support**

To address the skill mismatch and shortage of skilled labor, government should consider providing incentives for public and private investment in essential research, training, and education in pharmaceuticals and related fields. Investment is inevitable to address brain drain, pharmacy graduates and other necessary experts leaving the continent can significantly contribute to pharmaceutical research and production [48]. For the African pharma sector to thrive in the global market, it is inevitable for the industry to actively engage in research and development, however without proper collaboration with academia in the areas of APIs, stoichiometry, dosage form design technology and other advanced delivery techniques the skills gap cannot be curbed leading to stunted growth of the industry [49]. With government support and facilitation of extensive research through investment on novel edge cutting pharmaceutical processes and productions, there is hope for the general competitiveness of the Africa pharmaceutical industry [50–55].

### **Regulatory Reforms**

Policy regimes are key to improving the skill level in the pharma industry. Therefore, there is need to establish streamlined regulatory processes and clear guidelines for a progressive policy philosophy and to attract more professionals to the industry [30]. Creating agencies, such as the National Skill Development Authority in Bangladesh that aid in communication between the industry stakeholders and policymakers and assist in aligning policies conducive to skill development could be useful for inter-agency cooperation [31, 32]. These agencies can foster the development and implementation of education and training policies focused on meeting the skills gap in the pharmaceutical industry by collaborations with academia bodies and technical and vocational training institutes [33].

### **Leveraging Technology**

#### ***E-Learning Platforms***

Utilizing online platforms capable of designing and developing technology-based learning solutions for pharmaceutical and healthcare companies can make education more accessible to a wider audience for training. For instance, platforms, such as India – G-Cube, with more than 20 years of eLearning industry experience is among many fast growing companies in the online learning space [23].

#### ***Digitalization***

Pharmaceutical companies can adopt essential software tools and digital technologies that will enable rapid skills development in the manufacturing processes to mitigate the impact of the skills shortage and lessen the time required to get frontline workers to speed with present complex validation protocols in the industry [27, 56]. Digitalization can also be employed in capturing the invaluable on-the-job knowledge and vital skills of the experienced workforce that has been collected and honed throughout their careers before retirement and in so doing closing the skill gap [28].

### **Regulatory Fragmentation**

With 54 sovereign states, Africa has diverse regulatory systems and standards. The fragmentation in regulations and standards creates an unsnarling environment for harmonization in improving local production and investment. As it is challenging for pharmaceutical companies to navigate and comply with all the diverse standards and regulations deterring local production [29, 30]. There are three main challenges faced by the African pharma industry in achieving regulatory harmonization. Lack of human, financial, and technical resources in the regional body, poor implementation practices of

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regional policies by the National Medicines Regulatory Agencies (NMRA) and weak regulatory oversight capacity in the regional body [31].

Challenges associated with regulatory fragmentation can be overcome by adopting and implementing a pharmaceutical regulatory frameworks by all regional economic communities (REC) and development of pharmaceutical regional strategies in line with the Pharmaceutical Manufacturing Plan for Africa (PMPA) [27–32, 46]. Additionally, adoption and initiation of the Medicines Regulatory Harmonization (MRH) Program by REC to promote regulatory harmonization within their regions and developing regional centralized medicines regulatory and oversight bodies is essential to stimulate growth in the pharmaceutical sector [47].

Bodies, such as the African Medicines Regulatory Harmonization (AMRH) aim to harmonize and streamline the diverse regulatory systems and standards across the continent. Adoption and implementation of pharmaceutical regulatory frameworks would be beneficial in numerous ways including:

- aiding some member countries with tedious and expensive registration processes for pharmaceutical products. Challenges, such as high renewal fees every 2 years for pharmaceutical companies is an impediment to research [27];
- capacity building of already established farming sites in Africa for enhanced production of raw materials (APIs and excipients) for cost effective drug manufacturing;
- presence of regulatory oversight bodies potentially attracts investors and makes the investment process much more efficient [13, 50].

### **Counterfeit Drugs Circulation**

With high dependency on importation of pharmaceutical products the challenge of substandard drugs in the continent is significant. Poor implementation of policies by government has exacerbated this challenge [51]. Additionally, weak regulatory oversight associated with massive corruption practices at border posts of the region are enabling factors for smuggling of substandard and counterfeit medicines. Furthermore, the World Trade Organization (WTO)-TRIPS (trade related aspects of intellectual property) agreement could also result in low availability of drugs due to increased costs and consequently a rise in counterfeit drugs on the market. This explains the WHO reporting that 42% of falsified drugs cases occur in Africa [52]. This increase in circulation of counterfeit medicines in Africa has led to loss of 40% revenue for pharmaceutical companies [53].

With the NMRAs operating at WHO maturity level 3 there is noticeable transformation in the medicines regulatory landscape in Nigeria, Tanzania, Ghana, and Egypt [33]. The NMRA's surveillance effort to reduce the circulation of fake and counterfeit medicines is, however, undermined. To effectively overcome this challenge in the African pharmaceutical market [54], there is need to invest in strengthening medicines supply chain systems. Establishment of passive and active surveillance of drugs in circulation by employing people-centred technological innovation and closing open drug markets [51–53].

### **Technological Advancements**

With the current advancement in technology and artificial intelligence enabled momentum, novel digital technologies offer substantial opportunities that can be employed in mitigating some challenges faced by the African pharmaceutical industry, such as falsified pharmaceutical products on the market and inefficiencies in supply chain management. The potential of technology in transforming the pharmaceutical industry is evident by the growth of electronic pharmacy platform use in countries, such as Ghana [27, 57].

## CONCLUSIONS

While the African pharmaceutical industry presents with complex challenges, it also provides opportunities for innovation and growth with collective efforts streamlined at intensifying local production, regulatory harmonization, and leveraging technological advancement. This can potentially transform the industry into a sufficient system able to meet its healthcare demands. Support by the global pharmaceutical community, policy makers, and stakeholders are essential in addressing these challenges and consequently building a resilient industry.

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