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Challenges and Solutions for Local Pharmaceutical Production in Tanzania

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Abstract

The Tanzanian Pharmaceutical industry is one of the fundamental pillars of the country's healthcare system, yet it largely suffers from a set of challenges, including competing with low-cost imported pharmaceutical products. Despite the growing demand for pharmaceutical products driven by urbanization and universal healthcare initiatives, local manufacturers supply only 20% of the population's demand, leaving the rest of it covered by foreign producers. This study examines the challenges limiting the competitiveness of Tanzania's pharmaceutical sector, including high production costs, reliance on imported raw materials, regulatory hurdles, infrastructure limitations, and an influx of cheaper imports. Using a mixed-methods approach, including qualitative interviews with key stakeholders and quantitative data analysis, the study identifies key barriers and explores potential strategies for strengthening local production. Findings indicate that policy support, improved infrastructure, technology upgrades, and financial incentives are essential to enhancing Tanzania's pharmaceutical self-sufficiency. The study also highlights opportunities for growth and suggests that lessons from other African countries could inform policy interventions. Addressing these challenges could not only improve access to essential medicines but also drive economic growth and healthcare resilience in Tanzania.

Keywords

Health Systems, Local Manufacturers, Pharmaceuticals

1. Introduction

The pharmaceutical industry plays a critical role in Tanzania's healthcare system

and economic development by ensuring the availability of essential medicines and creating employment opportunities (Mori & Robberstad, 2012; Mhamba & Mbirigenda, 2010). Although Tanzania has made progress in developing its pharmaceutical industry over the years, this growth has been inconsistent. For instance, in 2009, 33% of the medicines consumed in Tanzania were locally produced, but this figure declined significantly to 10% - 20% in 2016. This decline in local production has increased the country's reliance on imports, with the Tanzania Medicines and Medical Devices Authority (TMDA) reporting that approximately 54% of the imports come from India, followed by Kenya and China at 6.3 and 5.8%, respectively (Wangwe et al., 2014).

Tanzania has a population of over 61.7 million people, making it one of the biggest markets for pharmaceutical products in Eastern Africa (TDHS-MIS, 2022). The demand for medicines has extensively increased due to urbanization, high disease burden, and campaigns made to achieve Universal Health Care. Such initiatives have brought a shift in health-seeking behavior from traditional methods to the use of healthcare facilities. This variation adds to the burden that the local manufacturers are facing since they do not have enough supply to cover the market needs.

Several initiatives, including encouraging investments from Indian generic drug makers and regulatory reforms, have been put forth by the government to improve the industry's self-reliance (MOHSW). To date, there are at least 42 medical manufacturing facilities, of which 18 deal with pharmaceutical products and the other 24 deal with medical devices (Fimbo et al., 2024). Despite the promising digits, there is still a significant gap in the production capacity of the local firms in Tanzania compared to their international counterparts. As the world's leading exporters, China and India have 5000 and 10,500 drug manufacturing companies, respectively.

This paper explores the challenges and solutions for local pharmaceutical production in Tanzania by examining the current state of the industry and identifying key factors affecting its competitiveness.

2. Materials and Methods

This study used a cross-sectional design that provided a snapshot of the local pharmaceutical manufacturing situation. (Creswell & Clark, 2010; Saunders & Bezzina, 2015) Both qualitative and quantitative approaches were used to gather data on production costs, market share, and competitive dynamics. Additionally, a desk review was conducted where existing literature, reports, and policy documents were examined.

2.1. Study Area

The study was conducted in Dar es Salaam, the central hub for pharmaceutical activities in Tanzania. The selection of this study site was methodologically justified by the geographic concentration of key stakeholders, including national reg-

ulatory bodies and major pharmaceutical manufacturers, within the city. As the primary locus of pharmaceutical production, distribution, and governance, Dar es Salaam offers unparalleled access to critical institutional and industrial actors in Tanzania, ensuring comprehensive data collection and contextual relevance to the study's objectives.

2.2. Sampling

Participants for this study were identified through purposive sampling (Allen, 2017; Saunders, 2012; Yin, 2003). Governmental stakeholders (n = 8) were recruited from three key regulatory bodies: the Tanzania Medicines and Medical Devices Authority (TMDA), the Medical Stores Department (MSD), and the Pharmacy Council (PC). Additionally, representatives (n = 16) were selected from domestic pharmaceutical manufacturing enterprises. The inclusion criteria prioritized participants' professional tenure, decision-making roles, and direct involvement in policy or operational processes. This sampling framework ensured the collection of contextually rich data from informants whose insights directly aligned with the study's focus on competitiveness barriers and industrial dynamics.

2.3. Data Collection Methods

For the qualitative component, data were collected through key informant interviews (KII) with government officials from the regulatory authorities and in-depth interviews (IDI) with officials from the local pharmaceutical industries. A total of 16 participants were included in the study. Four local pharmaceutical companies and four regulatory bodies presented two representatives each. The selection of the four pharmaceutical companies was based on two main criteria: geographical location and operational activeness. All four companies were located in Dar es Salaam, which is the commercial hub of Tanzania and home to the highest concentration of pharmaceutical manufacturers in the country. At the time of the study, these companies were actively engaged in production, unlike several others across the country that were either not operational or producing intermittently. Furthermore, the selected companies shared similar characteristics in terms of drug manufacturing processes, capacity, and product types, making them appropriate for comparative analysis and ensuring consistency in the data collected. The purposeful selection of these companies thus allowed for an in-depth exploration of key operational, regulatory, and market dynamics affecting pharmaceutical production in Tanzania.

In-depth interviews involved face-to-face interactions with key staff from local pharmaceutical industries. To ensure privacy and confidentiality, IDIs were conducted in the respective offices of the interviewees. The questions were semi-structured, allowing for open-ended questions to explore participants' insights into pharmaceutical management systems, manufacturing capabilities, production capacities and challenges facing the manufacturing of pharmaceuticals.

For quantitative data, the study analyzed data from Service Provider Assess-

ment (SPA) surveys of 2006 and 2015, specifically focusing on the availability of essential medicines in Tanzania. This involves statistical analysis of pre-existing datasets, which can be obtained from the DHS website (https://dhsprogram.com/data/available-datasets.cfm?ctryid=39).

Desk Review: The study also employed a desk review whereby we conducted a thorough examination of reports related to the production of essential medicines, policy documents, and relevant studies on local pharmaceutical industries in Tanzania.

3. Results

Tanzania's domestic pharmaceutical manufacturing industry has several obstacles that the study found seriously impair its capacity to compete with low-priced imports from outside markets. These difficulties include market competition, legal barriers, budgetary limitations, and operational inefficiencies. The following important points were emphasized.

3.1. High Cost and Price Fluctuations of Raw Materials

Tanzanian pharmaceutical manufacturers face systemic cost disadvantages due to heavy reliance on imported raw materials, including Active Pharmaceutical Ingredients (APIs), excipients, and packaging supplies, according to this study.

The pharmaceutical packaging and raw materials costs in various nations have been investigated, revealing that raw material costs in nations with large-scale production and stronger economies are significantly lower than those in Tanzania. As shown in Table 1, the unit costs of these inputs in Tanzania are generally 50–100% higher than in India and China, primarily due to import tariffs and limited local sourcing options.

Table 1. Comparative raw material costs for pharmaceutical manufacturing.

	Tanzania (USD)	India (USD)	China (USD)	Kenya (USD)
Paracetamol API	70	35	40	60
Ibuprofen API	90	50	55	85
Amoxicillin	50	30	40	45
Vitamin B12 supplements	120	75	85	110
Packaging (per unit)	0.15	0.08	0.10	0.12

Source: World Bank, 2023.

The elevated costs of imported raw materials and packaging (Table 1) not only limit Tanzanian manufacturers' competitiveness in regional and global markets but also exclude them from government tender processes. One participant explained that their company strategically withdraws tender processes due to the significantly higher production costs faced by local manufacturers, compared with larger companies from India and China.

No, we are not involved in government tenders. Our focus is solely on the local and international markets. We cannot participate in the tender and compete with big companies from India and China, our production costs are very high, and it costs to get raw material and compete. (*IDI* 10_2024)

This situation further entrenches foreign dominance in Tanzania's pharmaceutical sector, as imported medicines continue to flood the market through government contracts.

In addition to the high cost of raw materials, this study also highlighted that price fluctuations driven by external factors, such as variations in the dollar exchange rate, significantly affect market stability. These unpredictable changes in raw material costs pose a consistent challenge to production planning and budgeting, emphasizing the need for strategies to mitigate financial risks associated with market volatility.

The availability of raw materials isn't exactly easy, but it's not overly complicated either. The main challenge lies in the cost, as prices fluctuate due to external factors, including changes in the dollar exchange rate, which can impact market prices. (*IDI* 03_2024)

3.2. Irregularity of Power Supply

This study also identified irregular electricity supply as a critical barrier to pharmaceutical production in Tanzania. The power outages disrupt manufacturing processes, leading to unplanned downtime and damaging essential machinery. These disruptions directly reduce output capacity and operational efficiency, as highlighted by one participant:

The main problem is the irregularity of the electrical supply, which seriously reduces output. Machine destruction due to irregularity of electricity has also decreased efficiency, so delaying production goals. (*IDI* 09_2024)

The compounding effects of unreliable power—production delays and increased maintenance costs—have impaired the sector's ability to meet domestic demand and compete in time-sensitive markets. Therefore, addressing electronic power instability is essential to stabilizing production cycles and improving industrial competitiveness.

3.3. Technological Limitation

This study also revealed that technological limitations significantly hinder production efficiency and regulatory compliance in Tanzania's pharmaceutical industry. Many local manufacturers rely on outdated equipment and manual production systems, which limit their ability to meet the stringent standards set by the Tanzania Medicines and Medical Devices Authority (TMDA). For example, some manufacturers continue to use legacy machinery that lacks automation capabilities, leading to inconsistent product quality and frequent production delays. This reliance on older technologies not only reduces production efficiency but also increases operational costs due to frequent maintenance and energy ineffi-

ciency. A case point is the reported struggle of certain local pharmaceutical firms to upgrade their facilities to meet Good Manufacturing Practice (GMP) standards, resulting in limited product portfolios and reduced competitiveness against imported medicines. During an interview with production manager at one of the local manufacturers, he noted that.

Outdated technology. One of the main challenges we face is meeting the technological standards required by TMDA, particularly regarding quality, equipment, and adherence to specific guidelines. Since we rely on outdated technology, it is difficult to consistently meet these standards. This gap between our current capabilities and the required technological benchmarks remains a significant challenge for us. (*IDI* 08_2024)

3.4. Lack of Supportive Policies

This study also identifies a critical lack of policy frameworks to protect and promote domestic pharmaceutical manufacturing in Tanzania. Despite local producers' efforts, the absence of import restrictions, tax incentives, and procurement preferences for locally made medicines allows low-cost foreign alternatives to dominate the market, putting significant pressure on domestic producers' prices. This problem is most noticeable when it comes to necessary medications like paracetamol.

The lack of supportive policies prevents the country from fully replacing imports with locally produced drugs. While there are no restrictions on imported medicines, the influx of cheaper imported drugs floods the market, undercutting local producers. This results in pricing challenges, making it difficult for domestic manufacturers to compete, particularly with essential drugs like paracetamol. (*IDI* 07_2024)

3.5. Regulatory Bottlenecks

Systemic regulatory challenges still exist, even though the local manufacturing enterprises appreciate the substantial efforts made by regulatory bodies, including the Chemistry Department, PC, NEMC, TBS, TMDA, and others, to ensure cooperation. The high taxes imposed by the Tanzania Revenue Authority (TRA) are a major concern. As has been mentioned, these taxes directly contribute to increased production costs, which, in turn, drive up the prices of medicines. This rise in prices weakens the competitiveness of locally manufactured pharmaceuticals, particularly in comparison to cheaper imports.

Moreover, high import duties further compound the challenges of acquiring raw materials. The longer containers remain at the port, the more the company incurs extra charges, adding to the financial strain. These cumulative costs place local manufacturers at a disadvantage and hinder their ability to operate efficiently.

If a container takes 60 to 80 days to clear at the port, it's a big loss for us. Just obtaining assessment documents from various authorities can take more than 20 days. There are multiple authorities involved in the assessment, and once you receive the documents, you still need to process payments through the system,

which adds further delays. (*IDI* 01_2024)

This study also identified logistical inefficiencies as a critical barrier to Tanzania's pharmaceutical sector, particularly in raw material procurement and distribution. Key challenges include extended shipment lead times, port clearance delays, and inadequate transport infrastructure, which collectively disrupt production schedules and inflate operational costs.

This study also identified delays in cargo clearance at the port as a major bottleneck in production operations. These delays, which can extend up to three weeks, significantly disrupt production schedules and hinder the timely availability of raw materials. Although the Government Procurement Services Agency (GPSA) is responsible for addressing this issue, their efforts have been insufficient in resolving the problem. The prolonged clearance times pose a serious risk to operational efficiency and highlight the urgent need for improved logistical processes to ensure smoother supply chain management.

Delays in cargo clearance at the port, often stretching up to three weeks, severely disrupt our production schedule. Although the GPSA is tasked with handling this issue, their efforts have been inadequate. The prolonged wait for raw materials remains a critical challenge that hampers timely production and poses a significant risk to our operations. (*IDI* 05_2024)

3.6. Opportunities for Improvement and Recommendations

This study also highlighted significant opportunities for the local pharmaceutical manufacturing sector in Tanzania, particularly driven by consistently high demand for pharmaceutical products.

There is a significant opportunity to increase production due to consistently high demand. Despite the challenges we face, all our products are selling, indicating a strong market presence. At times, demand exceeds our production capacity, though there is no specific season for these peaks. Demand fluctuates with no consistent pattern and tends to rise and fall unpredictably. Notably, pain medications are the most frequently requested drugs compared to other types throughout this period. (*IDI* 06_2024)

Local manufacturers suggest that to boost local production, there is a need to restrict imports of medicines that can be produced domestically, preventing market saturation and supporting local industry growth. Addressing the issue of "cheap imports" and encouraging local manufacturing could stabilize prices and improve market opportunities for domestic producers.

Local pharmaceutical manufacturing depends on supportive policies limiting the importation of some drugs that domestic manufacturers can produce. Limiting the import of these medications would help local businesses to flourish. Without such limits, however, local producers must contend with strong competition from less expensive imports, which frequently have lower manufacturing costs because of reduced overhead and smaller workforce. Authorities must understand the need for local manufacturing and apply policies supporting and safeguarding

home production if they are to promote development. (*IDI* 09_2024)

Another participant highlighted the importance of supportive policies in promoting fair competition within the pharmaceutical industry. They emphasized the need for regulatory measures to manage imports, ensuring local producers can compete on equal footing with international suppliers. Additionally, policies aimed at protecting and strengthening local industries are seen as crucial for fostering growth, building capacity, and enhancing self-reliance in the sector.

Supportive policies to enhance fair competition. Policies must be in place to regulate imports, ensuring a level playing field between local producers and importers. Additionally, policies that protect and build the capacity of local industries are essential for fostering growth and self-reliance in the pharmaceutical sector. (*IDI* 02_2024)

The study emphasizes recommendations from local manufacturers, calling for stronger government support to enhance domestic pharmaceutical production. Manufacturers advocate for improved industrial policies, streamlined raw material acquisition, and better infrastructure to address delays.

To boost domestic production of essential medicines, the government should focus on empowering existing producers and creating a favorable environment for new ones. This includes developing supportive industrial policies and enhancing cooperation with stakeholders. Investment support for current stakeholders is crucial to strengthen their capabilities. Additionally, addressing delays in raw material acquisition is vital. The government should improve efforts to ensure timely availability of raw materials, whether sourced locally or internationally, by expediting transportation through ports and roads. Our primary strategy is to replace our outdated machines with modern equipment to boost production. This is our top priority, and we are actively seeking partnerships and investors to help achieve this goal. (*ID* 04_2024)

Local manufacturers emphasize the critical need for addressing financial barriers to improve productivity. They highlight the importance of ensuring easier access to capital, particularly through streamlined processes within financial institutions such as banks. Simplifying loan acquisition and providing favorable terms could enable manufacturers to invest in modern equipment, expand operations, and address other operational challenges. Enhanced access to capital is seen as a foundational step in driving growth and strengthening the local pharmaceutical sector's competitiveness.

To improve productivity, it's crucial to address key factors such as capital availability. Access to capital through banks should be streamlined. (*IDI* 08_2024)

The desk review revealed several models that exist for domestic pharmaceutical manufacturing in sub-Saharan Africa, ranging from government-supported initiatives to private sector investments. These models aim to reduce reliance on imported medicines, improve health outcomes, and boost local economies. Key aspects include government support for infrastructure, regulatory frameworks, and access to finance, as well as private sector collaboration and partnerships. The re-

view revealed different models of Pharmaceutical Manufacturing in Sub-Saharan Africa. The first model is the Government-Supported Initiatives, which includes different aspects such as the Regional Pharmaceutical Manufacturing Plans**.** Some regions, like the East African Community (EAC), have developed regional plans to foster pharmaceutical manufacturing within their member states, according to the United Nations Industrial Development Organization (UNIDO). These plans often involve government investment in infrastructure, regulatory support, and incentives for local producers. Another aspect of this model is public-private partnerships (PPPs), in which governments can partner with private sector companies to establish or expand pharmaceutical manufacturing facilities, potentially sharing investments and risks. The last aspect of this model is incentives and import controls, which allow governments to offer tax breaks, subsidies, or import restrictions to encourage local production.

Another model is Private Sector Investments, which has different aspects, such as the Local Pharmaceutical Manufacturers. Some countries have a growing number of local pharmaceutical companies, often focusing on generic drug production, according to a report from UNIDO on the pharmaceutical industry in sub-Saharan Africa. This model also includes Foreign Investment whereby Large pharmaceutical companies, like Aspen Pharmacare, may invest in manufacturing facilities in sub-Saharan Africa to tap into the growing market and reduce dependence on imports, as noted by UNIDO.

The last model, according to this study desk review, is Regional Collaboration, which includes aspects like Regional Pharmaceutical Manufacturing Networks**.** Countries within a region can collaborate to share resources, expertise, and infrastructure to boost local pharmaceutical production, as suggested in a report on the EAC Regional Pharmaceutical Manufacturing Plan of Action. Another aspect of this model is Joint Procurement, in which regional bodies can pool their purchasing power to negotiate better prices for APIs and raw materials, as discussed in UNIDO's guide on promoting pharmaceutical production in Africa.

4. Discussion

The findings of this study underscore several challenges hindering the competitiveness and growth of Tanzania's local pharmaceutical manufacturing sector. These challenges span operational inefficiencies, financial constraints, regulatory bottlenecks, and technological limitations, aligning with global literature on barriers to pharmaceutical production in developing economies.

The high cost and price volatility of raw materials emerged as a significant challenge for Tanzanian pharmaceutical manufacturers. Dependence on imported Active Pharmaceutical Ingredients (APIs), excipients, and packaging materials places a financial strain on local manufacturers, as global price fluctuations and high import tariffs exacerbate costs. Similar trends have been reported in studies on pharmaceutical industries in Sub-Saharan Africa, where import dependency has been identified as a key barrier to cost-effective production. For instance, In-

dia and China benefit from economies of scale, allowing them to produce and export APIs at lower costs, while Tanzanian manufacturers face elevated costs due to smaller production volumes and tariff policies.

Moreover, unpredictable changes in exchange rates further contribute to cost variability, complicating production planning and budgeting. Studies on currency fluctuations in developing economies emphasize their destabilizing effects on import-dependent industries, including pharmaceuticals (Munyoro & Mapfunde, 2023). Addressing these challenges requires strategic policy interventions, such as tax incentives and subsidies for raw material imports, as successfully implemented in countries like Kenya and Ethiopia (Mwangi et al., 2024).

Regulatory hurdles were highlighted as a major bottleneck in this study. Lengthy procedures for obtaining licenses, clearing raw materials at ports, and overlapping responsibilities of multiple regulatory bodies significantly delay production timelines. Similar findings have been reported in studies examining pharmaceutical regulatory frameworks in Africa. For example, (Owusu et al., 2022) identified delays in regulatory approvals as a key impediment to pharmaceutical industry growth in Ghana.

Additionally, logistical inefficiencies, including prolonged cargo clearance times and unreliable transport systems, exacerbate production delays. **Table 2** demonstrates that Tanzania's average time to market (12 - 18 months) significantly lags behind countries like Egypt and South Africa, highlighting the need for infrastructural improvements. Scholars have recommended streamlining regulatory and logistical processes to enhance efficiency and reduce operational costs (Mhamba & Mbirigenda, 2010; Wangwe et al., 2014).

Table 2. Average time to market for pharmaceutical products.

Country	Time to Market (Months)
Tanzania	12 - 18
Kenya	9 - 12
South Africa	6 - 9
Nigeria	15 - 18
Egypt	6 - 8

Source: World Bank, 2023.

The reliance on outdated technology was another critical challenge identified in this study. Local manufacturers struggle to meet the quality and regulatory standards set by the Tanzania Medicines and Medical Devices Authority (TMDA) due to technological constraints. This finding aligns with research by (Fimbo et al., 2024), which emphasizes the role of modern technology in achieving consistent product quality and regulatory compliance.

Countries like India have overcome similar challenges by investing in technology transfer and public-private partnerships to modernize pharmaceutical manufacturing (Patel et al., 2019). Tanzania can draw lessons from these approaches, lev-

eraging initiatives like the African Pharmaceutical Technology Foundation (APTF) to facilitate technology transfer and capacity building.

The unrestricted importation of low-cost medicines has saturated the Tanzanian market, creating substantial pricing pressures for local manufacturers. This is consistent with findings from studies on the pharmaceutical industries in Nigeria and Uganda, where weak policy frameworks have been linked to market saturation and uncompetitive local production (Fimbo et al., 2024). Effective implementation of policies limiting imports of medicines that can be produced domestically could help stabilize prices and foster local industry growth. Supportive industrial policies, including tax incentives, subsidies, and preferential procurement for local manufacturers, have proven successful in countries like South Africa, where they have strengthened the domestic pharmaceutical sector (Fimbo et al., 2024).

5. Recommendations

Despite these challenges, the study highlighted significant opportunities for Tanzania's pharmaceutical sector, particularly the high demand for essential medicines. This finding is consistent with global trends, where the rising prevalence of chronic diseases and increasing healthcare needs are driving demand for pharmaceutical products. To capitalize on these opportunities, local manufacturers advocate for enhanced access to capital, streamlined loan processes, and investment in modern equipment. Studies have shown that access to affordable financing is critical for scaling operations and improving productivity in the pharmaceutical industry.

The findings of this study emphasize the importance of government support in addressing the challenges faced by local manufacturers. Key recommendations include reforms in policy, implementing policies to regulate imports, and providing tax incentives for local manufacturers. Lessons can be drawn from Ethiopia's pharmaceutical sector, where policy reforms have fostered local production and reduced import dependency (Gebre-Mariam et al., 2016; Suleman et al., 2016). Participants have also recommended the development of Infrastructure to Improve transport systems and expedite cargo clearance at ports to enhance supply chain efficiency. Countries like Rwanda have successfully reduced logistical bottlenecks by investing in digital port management systems (Capitani et al., 2016). Another recommendation was on the technological upgrades. Facilitate technology transfer through partnerships with international stakeholders. The APTF offers a platform for accessing advanced technologies and building industrial parks, which could modernize Tanzania's pharmaceutical manufacturing capabilities.

6. Conclusion

This study provides valuable insights into the challenges and opportunities facing Tanzania's pharmaceutical manufacturing sector. Addressing the identified barriers through targeted policy interventions, technological modernization, and infrastructure improvements can strengthen the sector's competitiveness and enhance its contribution to national health and economic development. By leverag-

ing international partnerships and building local capacity, Tanzania has the potential to become a regional leader in pharmaceutical production.

Data Availability Statement

The original contributions presented in the study are included in the article/supplementary material. Further inquiries can be directed to the corresponding authors.

Ethics Statement

Ethical approval was obtained from the National Institute of Medical Research (NIMR), Tanzania, which was given the number NIMR/HO/R.8a/Vol.IX/4570 and from the Ifakara Health Institute (IHI), the project implementing organization with number IHI/IRB/No: 03-2024.

Author Contributions

FM drafted the manuscript, and OJ reviewed the manuscript. All authors contributed to the article and approved the submitted version.

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Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be constructed as a potential conflict of interest.

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