



TRANSFORMING
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A Case for Local Pharmaceutical Manufacturing in Africa in Light of the COVID-19 Pandemic

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1. Introduction

Industrialised nations have created mechanisms and policies to synchronise industrial and health interests (da Fonseca, 2017). The successful experience of, for example, Australia (Morgan et al., 2008) proves that health systems, when coordinated with technological development, can also generate goods and services that are crucial for economic development. Like many other low- and middle-income countries (LMICs), sub-Saharan African nations aspire to develop their pharmaceutical industry by promoting access to affordable quality medicine. However, African drug manufacturers often import machinery, packaging, and active pharmaceutical ingredients (APIs) because there is less indigenous production capacity. This is also hugely impacted by restrictive measures adopted by higher-income countries (Reichman, 2009).

Many countries are also taking restrictive measures during the current COVID-19 pandemic to secure adequate access to medical products including Personal Protective Equipment (PPE), such as masks, gloves, garments, medical devices (e.g., ventilators) and pharmaceuticals (e.g., Hydroxychloroquine, Paracetamol). These restrictive measures include export restrictions (e.g., India has restricted exports of 26 pharmaceutical components) and export authorisation (e.g., the European Union has introduced export authorisation measures that prohibit the export of PPE). These practices are hardly new. For example, in 2010, Hotez et al. argued that the failure of the global community to provide access to praziquantel—required for sub-Saharan Africa—was impeding sustainable development in the region (Hotez et al., 2010).

The lockdown of China and India, the largest producers of medical supplies in the world, due to the COVID-19 pandemic has resulted in a market gap. Indian companies supply 20 per cent of all basic medicine to Africa. The World Health Organization (WHO) has warned against the rising amount of counterfeit medicine in LMICs. Producers and suppliers are also struggling, as prices for the APIs to manufacture chloroquine tablets have sharply spiked, and certain companies cannot afford to keep going, especially in LMICs (Piranty, 2020).

Against such a backdrop, this paper will discuss the issue of scaling up the local pharmaceutical production in Africa as an opportunity, as well as a necessity, to tackle local epidemics of malaria, tuberculosis and Human Immunodeficiency Virus (HIV), as well as non-communicable diseases whose control could be undermined by the scale of the COVID-19 outbreak. The remainder of this paper will answer the following question: why should Africa manufacture pharmaceuticals locally? The discussion will consist of the methodology (Section 3), the importance of manufacturing medicine in Africa as a strategic solution (Section 4), the economic viability of local pharmaceutical production (Section 5), the key factors that enable the local manufacturing of medicine in Africa (Section 6), lessons learned from the current COVID-19 pandemic (Section 7), and a conclusion (Section 8).

2. Methodology

The study was supported by a review of literature from academic and practice sources to understand the prevailing insights in the area of research. Qualitative data were collected through the online survey and webinar. The survey

was conducted to collect relevant information from key stakeholder groups and was circulated through the International Association of Public Health Logisticians (IAHPL) platform. In total, 26 completed responses were received from five groups of key stakeholders:

- Representatives of the Ministry of Health in Nigeria (4%)
- Officials from parastatal agencies and central medical stores in Ethiopia, Liberia, and Tanzania (26%)
- Representatives from state-level health institutions in Kenya, Nigeria, and Tanzania (12%)
- Private-sector managers, including pharma in Kenya, Mali, Nigeria, Sudan, Tanzania, Uganda, Zambia (52%)
- Non-governmental organisations' representatives in Kenya and Nigeria (8%).

Additional data were also collected from key policymakers in Africa through a webinar held on 20 April 2020 and titled *African Leaders' Supply Chain Knowledge Exchange during COVID-19*. This highlighted country experiences in the current pandemic situation and reiterated why Africa should focus on local manufacturing of pharmaceutical products. The 20 participants of the webinar included African Health Supply Chain leaders (Chief Executive Officers, Director Generals, General Managers and Executive Directors) from Ethiopia, Malawi, Nigeria, Sierra Leone, South Africa, Tanzania, Uganda, and Zambia.

Purposive sampling was used to select the key participants both for the online survey and the webinar. This technique was used to ensure in-depth coverage of insights and experiences of the stakeholders who ranged from high-level strategic decision-makers to tactical planning, operational implementation, and external project consultants. The study was conducted based on set ethical guidelines, and informed consent was obtained from all the participants.

3. Why should Africa manufacture pharmaceuticals locally?

According to WHO Africa, the continent has 25.7 million people living with HIV/AIDS, and the region will experience a 27 per cent increase in the deaths from non-communicable diseases. The continent accounts for 24 per cent of the global disease burden (Ahen and Salo-Ahen, 2018). This is primarily because the region is undergoing a demographic transition, leading to increasing demand for safe, effective, and affordable health commodities (Gouda et al., 2019).

One of the first arguments commonly suggested by the advocates for local pharmaceutical manufacturing in Africa is that it will help resolve the issue of medicine accessibility, preventing discontinuities of medical supplies. Over the last decade, international funding has aimed to improve access to essential medicine on the continent, facilitating international procurement from Indian manufacturers as a cost-effective strategy for quality-assured medical products (Murray et al., 2010). Faced with numerous logistical, financial and capacity issues, Africa has increased its

reliance on the import of health commodities, accounting only for 3 per cent of global medicine production and importing between 95 per cent to 99 per cent of the required medicine (Coutinet, 2018).

In the context of the COVID-19 outbreak, this excessive dependency on imported pharmaceuticals can exacerbate issues faced by the African health sector. There has been a lead-time increase in the recommended procurement of health products. The sharp shortage of available medicine and increased procurement lead-times during the pandemic, since major exporting countries went into lockdown, highlighted the need for self-reliance in health infrastructure and pharmaceuticals as a national priority for Africa. The survey and webinar participants highlighted that 100 per cent of APIs for local pharmaceutical production in their respective countries are imported. The dependence on imported components extends to common pharmaceutical excipients, such as corn starch, magnesium stearate, and cellulose derivatives. If raw materials are not sourced locally, the global emergency, such as the current pandemic, can effectively shut down the local production lines. The need for creating a common pool of raw material sourcing for Africa and waving the movement restrictions of APIs as part of bilateral trade relationships or strategic alliances with foreign nations were commonly suggested as measures of preventing shocks to African healthcare systems during crises. The second issue that has been put forward in support of increasing the local production of medicine is affordability. Fragmented supply chains in Africa have an excessive number of intermediaries, forcing intermediary margins to account for up to 50 per cent of the final price in some countries (such as Kenya) and up to 90 per cent of the price in lower-income countries, compared to 2 to 24 per cent in the OECD countries (Tanani, 2018). Countries such as Ghana and South Africa have attempted to make drugs affordable through insurance schemes; however, they cover less than 8 per cent of the population of sub-Saharan Africa and do not cover prescription medicine on an outpatient basis.

Evidence from certain African countries suggests that local production can improve access and bring down the cost of medicine. In Cameroon, the high-tech generic drug production facility Cinpharm-Cameroon has allowed even a low-wage earner in the country to access a course of antibiotics at a lower price than their Kenyan counterparts. Similarly, in Ethiopia, a 20 per cent mark-up as a result of freight, duties and value-added tax can be avoided if the same drug is manufactured locally. However, there is also evidence that the prices for locally produced generic medicine can be higher than corresponding global prices (for example, in the case of Brazil [Nunn et al., 2007]).

4. Local pharmaceutical production: a strategic solution?

In 2005, a World Bank study revealed that South Africa, Kenya, Nigeria and Zimbabwe had demonstrated the industrial capacity for producing medicine for export or domestic consumption in the face of the diminishing supply of generic medicine from the major producers. Over the last decade, there has been an upsurge in policies to strengthen the local manufacturing of pharmaceuticals. In 2012, African Heads of State adopted the African Union Commission's Business Plan for implementing the Pharmaceutical Manufacturing Plan for Africa. In 2013, African leaders called for the strengthening of south-south cooperation to scale up investment in Africa's pharmaceutical manufacturing capacity, with a focus on generic essential medicine. In 2014, the Joint United Nations Programme on HIV/AIDS, the United Nations Industrial Development Organization and WHO came together to appeal to

Africa's development partners to support the scaling up of local production. These initiatives helped define and understand the scope of local manufacturing in the continent. As the centre of economic activity is shifting towards emerging markets, western pharmaceutical multinational corporations, and Asian generic manufacturers have started investing in developing production capacity within the continent. The primary drivers of growth will still be increasing disease burdens, the growth of health insurance schemes, an improved business climate, a mature regulatory environment and increased confidence in generic products (Chaudhuri et al., 2010).

However, Africa has a significant shortage of specialists to conduct clinical research. Providing comprehensive training to specialists in medicine development, regulatory sciences, and clinical research remains a major challenge for the continent's universities, industry and regulatory agencies. Adherence to Good Manufacturing Practices (GMP) is required to promote quality-assured medicine. However, regulators and authorities in resource-constrained countries still find it difficult to carry out periodic inspections and control the manufacturing and last-mile delivery of essential health commodities (Sigonda et al., 2017). In many African countries, such oversight bodies do not even exist. A partial solution to this has been provided by the WHO pre-qualification scheme supporting more advanced African manufacturers to achieve international standards. For example, the Quality Chemicals plant in Uganda has been the first to obtain WHO pre-qualification (Anderson, 2010) and the Universal Corporation in Kenya has been prequalified for its Lamivudine Zidovudine fixed-dose combination.

5. Is local production economically viable?

There is an increase in support for local pharmaceutical production, prompting Africa to decrease its donor dependency for medicine. Scoping initiatives have identified various benefits of local production. These include avoiding stockouts, supporting local incomes and jobs, triggering technology spill-overs and helping the sustainability of government medical schemes. However, the question of how economically viable and sustainable local production can become remains.

In sub-Saharan Africa, only Kenya, Nigeria and South Africa have a relatively sizeable industry with dozens of companies producing for their local markets and, in some cases, for export to neighbouring countries. Almost all of them, except two in South Africa and one in Ghana, import APIs from other manufacturers and formulate them into finished drugs. Up to 100 manufacturers in the region are limited to packaging, buying pills in bulk and repackaging them into consumer-size packs. Lower utilisation rates of production facilities, the unregulated structure of supply chains, low-quality production standards, high operating costs and human resources constraints outweigh most of the benefits of local production. The evidence suggests that Ethiopia and Nigeria can create potentially lucrative markets (Conway et al., 2019). An increased focus on quality and a stronger regulatory system would help fight against counterfeit, expired and substandard drugs, which are still common in the region. Additionally, attention to scale, the creation of regional hubs, a strategic focus on the drug-product formulation and upgrading existing value chains will help these countries build a local pharmaceutical industry. To attract more investment in the pharmaceutical sector, countries may have to shift to an active industrial policy that incentivises major players to move away from the relatively less risky alternative of importing. Given the uncertain and diverse economic, health

and market situation, any monolithic policy framework will be impractical for most of Africa. A flexible policy approach that allows for adapting to change may help convert some of the current support for the idea into augmented manufacturing capacity. For many treatment programmes, local production can be an important step towards sustainability, preparing the ground for mainlining access to medicine beyond the current era of drug donations.

6. Key factors enabling local manufacturing in Africa

Following the literature review highlighting successful experiences, such as in Brazil (da Fonseca, 2017; Kaplan and Laing, 2005; EAC, 2018), online survey responses, and webinar feedback the following enabling factors are suggested for establishing the local production of medicine and health technology in sub-Saharan Africa.

Political commitment: policies, plans and legislation will be necessary to create a pharmaceutical industry that is self-sufficient in medicine and medical supplies. This requires political commitment and thought leadership at the top level. The survey respondents from Ethiopia, Kenya, Liberia, Mali, Nigeria, Sudan, and Tanzania acknowledged that government support would boost local pharmaceutical manufacturing. Without such commitment, national production of pharmaceuticals will not flourish. Local manufacturing should be a national issue and therefore should not simply appear on the agenda of individual ministries. Policy provisions and legislations should include incentives to encourage and support investment in the development of the pharmaceutical industry and its commitment to high standards of good manufacturing practices. Development of local pharmaceutical manufacturing in Egypt and Cuba in the mid-1950s and Iran in the 1980s offer examples of such higher-level political commitment.

Coordination: pharmaceutical production is generally a shared responsibility between different levels of government and between different government authorities at the same level. Disintegration between them and the public sector bureaucracy significantly discourages investors, particularly foreign ones. Responses from Ethiopia and Kenya reiterated the need for improved collaboration amongst the different stakeholders. The establishment of one governmental authority that coordinates different governmental organisations could improve the situation. This authority should comprise representatives from related public organisations such as Ministries of Health, Trade, Industry, Land, Customs, etc. It should provide standardised information and procedures and foster proactive collaboration between ministries and government agencies engaged in the formulation of policies for the pharmaceutical sector (da Fonseca, 2017). This will also help in the harmonisation of regional markets across the continent and will help overcome the constraints encountered by countries of a smaller economic size (AMRH, 2011). Regional cooperation can induce sustainability in production and overcome the challenges of limited human capacity in certain regions (Mackintosh et al., 2018).

Investments: local production of pharmaceuticals and health products requires a vast investment in infrastructure, especially the road network, human resources, technology transfer, equipment manufacture, clinical research, access to raw material, etc. For example, Brazil has invested billions of dollars in local pharmaceutical industrial

development, including technology transfer agreements and financial assistance, while maintaining strong price control mechanisms to meet health goals (Shadlen and da Fonseca, 2013). The survey responses from Ethiopia, Mali, Nigeria, and Tanzania highlighted the requirement for sustainable investments to encourage local manufacturing. Investments to strengthen skilled labour to step up production was also seen as significant in Liberia, Mali, Tanzania, and Uganda. For many LMICs, power shortages are a common issue. In Nigeria, access to electricity and minimising power outages has been a problem for several decades. National governments need to approve policy and legislation that attracts national and foreign investors to the field. Such policy and legislation compel national development banks to offer long-term loans at low-interest rates to the investors in this industry, exempt imported materials, etc. However, a balance needs to be achieved to manage tensions between industrial and health policies (AUC, 2007). Both health and trade policies should be explicit and consistent with the overall development strategy.

Regulations: reforming regulatory policies is crucial for guaranteeing high-quality products in low- and middle-income countries, but governments must play a crucial role in supporting local firms to adapt to these regulations (da Fonseca, 2017) and in creating opportunities to support local firms to adhere to regulatory policies (Shadlen and da Fonseca, 2013). Effective regulatory systems contribute to better public health outcomes, and ineffective regulations can act as a barrier to access to healthcare. These regulations should include requirements that assure the safety, efficacy and quality of generic medicine and support the adoption of WHO's current GMP, widely known as cGMP (WHO, 2007). Strong regulations will help cater to local needs (WHO, 2011) and develop an independent, outcome-oriented, and judicious medicine regulatory authority (Riviere and Buckley, 2012).

The survey responses emphasised the need for stronger regulations to control generic imports in Kenya and Nigeria, control on counterfeits arriving from international markets, improved compliance to cGMP in Tanzania, and to enhance quality regulatory capacity in Ethiopia and Tanzania.

Pricing: to meet health goals, governments must establish strong drug price control mechanisms. However, studies show that local firms could be just as competitive as foreign-based manufacturers if they adopt lean manufacturing strategies combined with guaranteed market access conditions (e.g., Chaudhuri and West, 2014; CHAI, 2016). The survey respondents in Ethiopia and Kenya opined that controlling the cost of production by exploring local production of some APIs and leveraging on the existing petrochemical industry can provide cost advantages and bolster local manufacturing. A favourable tariff regime for raw materials and equipment and higher tariffs on imported brands combined with effective border control were also suggested as important steps to ensure competitive prices.

Know-how: building innovative public-private partnerships can stimulate technology transfer and voluntary licences (da Fonseca, 2017). Respondents in Nigeria, Tanzania, and Ethiopia echoed that governments need to pass policies that encourage the transfer of technology and technical know-how from multinational pharmaceutical companies to local manufacturers. These might include patented medicine, a mechanism where innovators could voluntarily give licences to their local partners to synthesise their APIs and formulate finished products in the long run. Building

local capacity for the manufacturing of APIs could begin with simple products, such as paracetamol, aspirin, etc., gradually pooling more resources at the country level.

Pooled procurement: This is a demand-driven process which would aid national manufacturers in market-shaping, as most of them import APIs that have an expiry date. The system would also help them develop annual production plans, utilise their full production capacity and expand both horizontally and vertically. Pooled procurement requires adjustments to the public procurement legislation, which in most countries mandates the government to buy products and services at the lowest available price. One survey respondent from Sudan informed that a pooled procurement system in Sudan increased the scale of procurement from US \$3 million in 2010 to US \$67 million in 2017. Another respondent from Nigeria, likewise, echoed the idea of pooling of resources at the African level.

Protection: governments should avoid protecting local manufacturers for several reasons. First, protection policies deny patients access to high-quality imported medicine at affordable prices. Second, it contradicts the principles of the World Trade Organization. Third, some countries are members of regional economic groups, such as the Common Market for Eastern and Southern Africa (COMESA).¹ Fourth and finally, protection of local production would compromise quality and increase prices for governments and end consumers, especially because most Africans pay for medicine out of their own pockets (EAC, 2018).

Competition: Health supply chains have become highly competitive due to increased globalisation, an influx of new technology, and evolving health demands. This has forced key stakeholders to rethink various strategies and alliances. The survey respondents identified certain policies which can support robust and well-functioning health supply chains by promoting competition at various levels. These included the elimination of middlemen along the value chain (Kenya), easing foreign currency process (Ethiopia), fostering the practice of prioritised buying of drugs from the local manufacturers over those outside Africa (Kenya and Zambia). Respondents in Ethiopia and Nigeria specifically highlighted the importance of instilling trust in locally produced pharmaceuticals, promoting awareness among the health facilities and the general public.

Based on responses to the survey and the discussion at the webinar, we suggest looking deeper into various enablers that were proposed as measures to boost local pharmaceutical manufacturing with the aim to better understand the country-level implications. This can help the design of country-appropriate strategies for strengthening local manufacturing. The following table (Table 1) enumerates the enablers as reflected by the survey respondents and underlines how countries in Africa will need to overcome inherent weaknesses to create a conducive environment for local pharmaceutical production. The table offers a host of factors which should be examined and compared against the country's degree of economic activity, health system, resilience, political stability, and the level of disease burden. The study recognises that, in the long run, a proper balance of key enablers will help countries in Africa become more locally sustainable and less vulnerable to external shocks.

¹ The member states of COMESA are Burundi, the Comoros, the Democratic Republic of Congo, Djibouti, Egypt, Eritrea, Ethiopia, Kenya, Libya, Madagascar, Malawi, Mauritius, Rwanda, Sudan, Swaziland, Seychelles, Uganda, Zambia and Zimbabwe.

Table 1: Key enablers for local pharmaceutical manufacturing in Africa

Enablers		Ethiopia	Kenya	Mali	Nigeria	Sudan	Tanzania	Uganda
Government support		√	√	√	√	√	√	√
Investments	Infrastructure			√	√		√	
	Research & development				√			
	Human resources			√	√		√	√
	Access to raw materials		√		√			
Regulations	Import controls		√		√			
	Control on counterfeit		√		√		√	
	Compliance to GMP				√	√	√	
	Quality control	√	√				√	
Pricing	Reduce cost of production	√	√					
	Leverage petro-chemical industry				√			
Know-how and technology transfer					√		√	
Collaboration		√	√					
Pooled procurement of resources					√	√		
Competition	Minimise intermediaries		√					
	Competitive market	√	√					
	Ease access to foreign currency	√						
	Improve trust in local products	√			√			

Source: Survey responses

7. COVID-19 Pandemic: Lessons learned so far

At the end of the online survey and the webinar, our experts were asked to reflect on the lessons their countries and respective organisations are learning from the COVID-19 pandemic as it unfolds. The most common theme in the survey responses and discussion was increasing self-reliance. As the pandemic has put national health systems to the test, health facilities and supply chains have come under significant pressure, worsening their underlying issues and deficiencies. The crisis underscored the risk of overreliance on international health supply chains, imported pharmaceuticals and donor support. As the world's largest producers and exporters of medical products introduced restrictive measures or closed their country borders, the need for a strategic alliance with key countries to ensure the

uninterrupted supply of vital medicines became more pertinent for Africa. Updating and improving policies and protocols for emergency responses was another commonly suggested outcome of this crisis, as well as the heightened necessity of strengthening the sub-national health infrastructure, coordinating the key players in health systems and increasing the robustness and agility of supply chains.

In a situation of considerable dependency on foreign pharmaceutical companies, Africa's mission is seen by our surveyed experts as bringing out local brands of medicine, turning to local professional experts and intensifying clinical research and trials. This means that local pharmaceutical manufacturing needs to be considered holistically. If local production is heavily reliant on imported APIs, excipients and additives, and manufacturing equipment, its robustness and reliability can be misleading, especially at the time of a global health crisis when import ceases, and local manufacturing effectively stops. The experts reiterated that technology transfer and local sourcing of technologies, as well as a stronger focus on improving the technical education and expertise in the health sector, are among the key steps in tackling future pandemics and improving healthcare on the continent.

8. Conclusion

Local production of pharmaceuticals in low- and middle-income countries has been at the top of the agenda of international organisations as a means to reconcile healthcare and industrial goals, and Africa is not an exception (see, for example, Murugi et al., 2010). This paper aims to send a message to African leaders and policymakers to set up a conducive environment for the national manufacturing of medical products. However, it should be noted that local manufacturing might not be able to produce cost-effective commodities in the short run. This has been seen in countries such as Zimbabwe and Mozambique. Setting up manufacturing facilities can nevertheless stimulate the development of local industries. Addressing an array of different issues requires coordinated action by multiple parties and facing these challenges remains a work in progress. Given the volatility of the economic, health and market situation, any uniform policy framework will be impractical for most of Africa. Revamping the capacity of local pharmaceutical manufacturing companies to produce APIs and biological medicine will remain a challenge in Africa for the foreseeable future, as will compliance with international standards, which varies significantly across the continent. However, under the right conditions and supported in the right manner, the countries have the potential to build a robust local pharmaceutical manufacturing industry.

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