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African Pharmaceutical Sector Landscape Analysis

Focus on Pharmaceutical Manufacturing and Trade under the AfCFTA

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List of Acronyms and Abbreviations

AfCFTA	African Continental Free Trade Agreement
Africa CDC	Africa Centre for Disease Control and Prevention
AfTra	Africa Trade Fund
AMA	African Medicines Agency
AMRH	African Medicines Regulatory Harmonization
AMU	Arab Maghreb Union
API	active pharmaceutical ingredient
APPM	African Pooled Procurement Mechanism
AUDA-NEPAD	African Union Development Agency - New Partnership for Africa's Development
CAGR	compound annual growth rate
CM	continuous manufacturing
COVID-19	Corona Virus Disease 2019
EAC	East African Community
EARAPA	East African Regulatory Affairs Professionals Association
ECOWAS	Economic Community of West African States
GCCs	global commodity chains
GPNs	global production networks
GVCs	global value chains
HIV/AIDS	human immunodeficiency virus /acquired immunodeficiency syndrome
ITC	International Trade Centre
MFN	most-favoured-nation (tariff rates)
NAFDAC	National Agency for Food and Drug Administration and Control
NMRAs	National Medicines Regulatory Authorities
NTMs	non-tariff measures
PAVM	Partnerships for African Vaccine Manufacturing
PMPA	Pharmaceutical Manufacturing Plan for Africa
PSC	pharmaceutical supply chains
R&D	research and development
RECs	regional economic communities
SADC	Southern African Development Community
SDGs	Sustainable Development Goals (of the United Nations)
USA	United States of America
USD	United States dollar
WHO	World Health Organization
WITS	World Integrated Trade Solutions (World Bank)
WTO-WCO	World Trade Organization/World Customs Organization

1 Executive Summary[1]

Industrial policy is not new to African countries – in the wake of the HIV/AIDS epidemic, many countries in Africa prioritised development of the pharmaceutical sector, with a focus on local manufacturing of antiretrovirals. It could be argued that this approach was not as successful as envisioned, since decades later Africa is still largely dependent on pharmaceutical imports.

The recent COVID-19 pandemic once again brought the fragility of health systems and lack of local productive capacity into sharp focus. This has led to high-level political commitments to address these issues in a more sustainable way. Policy interventions, such as the implementation of the African Continental Free Trade Agreement (AfCFTA) and the establishment of the African Medicines Agency (AMA), will go a long way to improve the development and growth of the sector.

Against this backdrop, there are several constraints that will need to be addressed to fully leverage the opportunities presented by these key policy interventions. This landscape analysis focuses on some of the key factors related to pharmaceutical manufacturing and trade. Regulatory harmonisation for the regulation of medicines across the continent is extensively covered in other reports and has therefore been excluded from this analysis. However, related factors which may have unintended negative consequences are discussed.

Policy recommendations are made related to pharmaceutical manufacturing and trade. Recommendations focus particularly on key areas that will facilitate further growth and competitiveness in the sector.

2 Background

Africa's pharmaceutical market has been predicted to grow rapidly. However, despite its potential, the market remains a fraction of that of similar demographics, such as China and India, which dominate the global pharmaceutical market (Banda et al., 2022; Banda, 2023, Conway et al., 2019). Industrial policy is not new to African countries – in the wake of the HIV/AIDS epidemic, many countries in Africa prioritised development of the pharmaceutical sector, with a focus on local manufacturing of antiretrovirals through industrial policy initiatives. In addition, similar objectives have been highlighted in Pan African policies, such as the Pharmaceutical Manufacturing Plan for Africa, developed by the New Partnership for Africa's Development (NEPAD) (now African Union Development Agency AUDA-NEPAD) (Byaruhanga, 2020).

The Pharmaceutical Manufacturing Plan for Africa (PMPA) was adopted in 2007 and was designed to catalyse local manufacturing of pharmaceutical products. The end objective was to expedite access to high-quality, affordable, essential medicines, as well as to derive economic benefits through a sustainable, self-reliant and competitive pharmaceutical industry (African Union 2013). Despite these policy interventions, decades later, Africa remains import dependent with limited pharmaceutical manufacturing capabilities focused mainly on generic medicines that require less complex technology.

The recent COVID-19 pandemic amplified the fragility of Africa's healthcare systems, with huge external dependencies including financing, infrastructure, technical and research capabilities, manufacturing capacity, and skilled human resources. More importantly, it has highlighted that public health threats, such as the COVID-19 pandemic, can have devastating impacts on populations and economies in Africa. These impacts accelerated key sector

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initiatives that were lagging in implementation previously, including those focused on regulatory harmonisation of medicines (African Medicines Regulatory Harmonization (AMRH) and AMA), local manufacturing of pharmaceuticals, particularly vaccines (Partnerships for African Vaccine Manufacturing (PAVM)) and development of regional value chains and trade (Africa Trade Fund (AfTra)) (Africa CDC, 2022; AMRH, 2024, AfTra, 2024).

Efforts are being made to strengthen local pharmaceutical manufacturing capacity in Africa, with a focus on improving the resilience of the pharmaceutical sector and health systems. Furthermore, there are initiatives to improve the performance of National Medicines Regulatory Authorities (NMRAs) which are crucial for the regulation and oversight of pharmaceutical manufacturing (Okezue et al., 2022). Local regulatory expertise is necessary to attract investment as African pharmaceutical manufacturers expand their product portfolios (Simpkin et al., 2019).

There has been a fair amount of scepticism about the competitiveness of local pharmaceutical manufacturing in terms of product pricing, quality and reliability of supply. Nevertheless, progress has been made in these areas indicating a positive trajectory for the industry (Bright et al., 2021; Okezue et al., 2022). Selected factors impacting pharmaceutical manufacturing and trade that affect further growth and development in the sector are discussed in this report.

3 Objectives

The overall objective of this landscape analysis is to provide an informed assessment, based on available data, of potential opportunities and challenges in further pharmaceutical sector development to achieve the objectives of trade and public health. Policy recommendations could contribute to enhancing the competitiveness and efficiency of the pharmaceutical value chain.

4 Landscape analysis

A significant amount of research, reports and general media publications have focused on pharmaceutical sector development in Africa since the COVID-19 pandemic. However, some practical aspects that directly affect pharmaceutical manufacturing and trade require further analysis and insight. Analysis of these factors can inform policy imperatives that need to be considered for further sector growth and competitiveness.

Informed by the United Nations' Sustainable Development Goals (SDGs) and WHO guidance to member states, overall international consensus exists on core pharmaceutical policy objectives, namely: (i) access and affordability; (ii) safety, efficacy, and quality; (iii) rational use of medicines, and (iv) local production capacity and health security.

This analysis has been conducted through the lens of opportunities and challenges in the context of the recent implementation of the African Continental Free Trade Agreement (AfCFTA), which calls for the development of regional pharmaceutical value chains. To fully leverage opportunities presented by the AfCFTA, key pharmaceutical policy dimensions need to be addressed (Signé & Munyati, 2023, p.14).

It should be noted that these areas are not all-encompassing and do not provide a comprehensive analysis of all factors affecting the pharmaceutical sector, but rather those that are considered important enough in their impact on local pharmaceutical manufacturing and trade.

4.1 Pharmaceutical manufacturing

Healthcare innovation progresses and populations in Africa have been confronted with unexpected public health threats, as demonstrated by experiences and impacts related to HIV/AIDS, tuberculosis, malaria, Ebola and most recently COVID-19. Consequently, we need to look at the agility and resilience of African healthcare systems, including pharmaceutical supply security to assess whether they are fit for purpose for the future.

The African continent has approximately 600 local pharmaceutical manufacturers to serve a population of about 1.3 billion people, 80% of which are concentrated in eight countries, including the Arab Republic of Egypt, Algeria, Morocco, Tunisia, Nigeria, Ghana, Kenya and South Africa (Bright et al., 2021; Okezue et al., 2022; Ussai et al., 2022). Most manufacturers focus on formulation manufacturing or finished product manufacturing, while active pharmaceutical ingredient (API) manufacturing is limited and therefore still largely imported.

South Africa's pharmaceutical manufacturing capacity has declined in recent decades, with consequent rise of imports of finished drugs produced elsewhere (Horner, 2022). At the same time, Ethiopia implemented its National Strategy and Plan of Action for Pharmaceutical Manufacturing Development and Improving Access in Ethiopia as an effort to enhance local manufacturing of pharmaceuticals. By comparison, China and India with a population estimate of 1.4 billion each have as many as 5000 and 10,500 pharmaceutical manufacturers respectively. Importation of medicines into China is approximately 5%, whilst that of India is about 20%.

Globally, multinational pharmaceutical companies withdrew manufacturing operations from markets around the world to concentrate production at ''centers of excellence'' elsewhere, involving large, lower-cost units benefitting from economies of scale and serving global markets. This consolidation of manufacturing has posed considerable challenges for pharmaceutical manufacturing in other markets as it meant that markets such as those in Africa are seen as end markets to sell already finished products into, rather than as locations for establishing manufacturing operations (Horner, 2022).

This globalisation of pharmaceutical value chains posed significant risks to security of supply of key healthcare commodities during the pandemic. Subsequent debates and policy responses have emphasised the need for development opportunities for the Global South through local firms becoming integrated into the global commodity chains (GCCs), global value chains (GVCs) and global production networks (GPNs) governed by leading multinational corporations. It also underscores the importance of local manufacturing to trade, economic growth and public health (Horner, 2014).

4.1.1 Active Pharmaceutical Ingredient (API) and excipient manufacturing

Active Pharmaceutical Ingredient (API) manufacturing consists of complex chemical and/or biological processes medicines and reactors for drug substance manufacturing for vaccines and has been influenced by global value chains, import orientation and the need to strengthen local pharmaceutical manufacturing capacity. All of these processes represent complexity, requiring specialised equipment, skills and therefore have high entry barriers to market (Horner, 2022).

The COVID-19 pandemic exposed vulnerabilities in upstream pharmaceutical supply chains (PSC). The global supply of APIs has also been a point of concern with the need to reduce dependency on few locations and large-scale batch manufacturing. Almost all APIs still need to be imported for purposes of local manufacturing. Lack of greater local API production in Africa can be partially attributed to competition from low-cost Indian and Chinese suppliers. Other production inputs, i.e. excipients are also largely imported. The imports of these production inputs are impacted by high transportation costs, currency fluctuations, demand fluctuations and import tariffs which add to overall production costs.

Quality and purity of APIs are critical in pharmaceutical manufacturing, with a focus on chemically complex processes which are highly regulated to ensure effectiveness, quality and safety in the final pharmaceutical product. API manufacturing is not labour-intensive but requires significant numbers of highly skilled workers such as pharmacists, chemists and engineers. Locally manufactured medicines need to then compete with low-cost, high-quality imports of finished medicines from countries like India and China, that also dominate the global markets for supply of production inputs with low manufacturing costs and highly skilled workforces (Banda, 2023; Horner, 2022; Tomlinson & Low, 2012).

The environmental impact of API manufacturing has been a significant concern with studies highlighting the emission of APIs into the natural environment during their manufacture and disposal. A recent study by Wilkinson et al. (2022) showed that the highest cumulative concentrations of pharmaceutical contaminants were found in rivers in low- and middle-income countries. Most contaminants were found in water samples from countries in Africa and Asia. African countries included Ethiopia > Tunisia > Democratic Republic of Congo > Kenya > Nigeria. Asian countries included Pakistan > India > Armenia > Palestine > China (Wilkinson, et al., 2022). Since Africa has 60% of the world's most arable land, it would be important to consider green approaches to API manufacturing to avoid unintended consequences of environmental pollution of harming the agricultural sector.

Research focusing on the feasibility of API manufacturing in Africa is limited, indicating various views of the feasibility of API manufacturing becoming cost effective and competitive in a globalised market with dependencies on a few locations. However, the critical need to establish health system resilience as well as to reduce dependency on imports of critical APIs for pharmaceutical manufacturing underscores the need to invest in API manufacturing capabilities. The evolution of pharmaceutical innovation towards more biological APIs and formulations has the potential to further increase complexities for investment in manufacturing capabilities (Aulakh et al., 2022; Fernández-Cabezón et al., 2018; Horner, 2022; Wilkinson et al., 2022).

Regulators hope to enable more dependable location decisions and improved processing quality with the adoption of advanced technologies such as process intensification through continuous manufacturing (CM). In practice, CM is most developed for drug product formulations, with fewer applications targeting the synthesis and separation/purification of APIs and intermediate chemicals (Aulakh et al., 2022; Horner, 2022; Wilkinson et al., 2022).

Locally produced APIs and excipients will complement the existing finished product manufacturing capabilities in African markets, provide security of supply of priority medicines, and stable pricing with less sensitivity to exchange rate fluctuations. Recently, Nigeria has announced plans for commercial manufacturing of four antimalarial APIs following technical collaboration with their National Agency for Food and Drug Administration and Control (NAFDAC) and Indian-based WHO prequalified API manufacturer partners. Other local manufacturers plan to initiate local manufacturing of different classes of widely used APIs and pharmaceutical excipients. These developments come in the wake of several more multinational pharmaceutical companies exiting their operations out of African markets (Aluh et al., 2024; East African Regulatory Affairs Professionals Association (EARAPA), 2024; Ezeagu et al., 2024; Uzor 2023).

4.1.2 Finished product manufacturing

The second main stage of pharmaceutical manufacturing is formulation manufacturing or finished product manufacturing, which is a physical process of adding excipients to an API and 'formulating' the drug into a consumable form such as a tablet, liquid, capsule, cream, ointment, or injectable. The entry barriers are much lower for this stage.

There is an inherent competitive challenge to promoting local industrial developments in a place like South Africa (and other African countries for that matter) that are primarily

incorporated into global value chains as an end-user market, rather than a local production site. Local manufacturers are small buyers of production inputs who are dependent on large foreign suppliers of APIs, many of whom are vertically integrated. Prices of imported medicines may in many cases be much lower than locally produced medicines (unless additional mark-ups are applied at other points in the supply chain), creating challenges to compete on price and scale. These factors can impact the viability of local pharmaceutical manufacturing and security of supply (Banda, 2023; Gleeson et al., 2019; Horner, 2022).

In addition, there are tensions between industrial policy interests in local manufacturing and health policy interests for broader access to medicines. Local pharmaceutical production has been viewed through a public health lens which seeks to maximise access to medicines at the lowest cost and highest quality, while industrial development interest focuses on the growth, productivity and overall economic value-add of the sector. This scenario illustrates a lack of coordination amongst policymakers who have competing views and interests on how the sector should be managed. As long as this remains the case, the full potential of the sector will not be realised.

4.1.3 Production environment

In many African countries, enabling infrastructure (such as access to continuous supply of electricity and clean water used in pharmaceutical manufacturing) can be problematic and costly. This can affect production volumes, product quality and security of supply. Major pharmaceutical companies have recently exited from African markets, mostly due to unfavourable operating environments (Aluh et al., 2024, Ezeagu et al., 2024). This does not bode well for the growth and attractiveness of pharmaceutical markets in Africa. On the positive side, these exits, in the face of rising demands for healthcare commodities, opens market opportunities for local players to enter.

Local manufacturers, however, face tariffs on the import of production inputs increasing the cost of production. Sourcing raw materials from proximate locations will be beneficial if local manufacturing of production inputs is prioritised. Lower-priced imported inputs may reduce costs and thus increase domestic production and exports. Other factors that are key to production (such as favourable tax regimes, uninterrupted power and water supply) will contribute to overall market attractiveness (Edwards & Jenkins, 2015; Tao et al., 2023).

Policymakers, however, need to consider market attractiveness and enablement as key factors that will contribute to establishing sustainable local manufacturing. High operating costs and complexity as well as competition with globalised value chains with key geographical concentration of raw material sources have the potential to exacerbate the increase in the overall cost of production, impact security of supply and add variation in carbon footprints through longer transportation distances.

4.2 Pharmaceutical trade

Intra-Africa trade in pharmaceuticals is a critical aspect of Africa’s economic and healthcare landscape. Lack of efficient trade in pharmaceuticals has economic consequences on the sector as well as public health impacts on populations.

International trade is considered as one of the major factors that positively contribute to economic growth and development. In this regard, Africa has lagged behind other regions in the world, as well as in terms of intra-Africa trade, which are relatively low at less than 20% in the regional economic communities (RECs), compared to other regions. More than 80% of African exports are destined for markets outside of Africa (Asiedu, 2021).

Gleeson et al. (2019) identified ten factors in trade agreements that can affect domestic pharmaceutical policy and regulation. Even though the current study does not focus on any trade agreements that include Africa, it is important to consider these factors in light of the AfCFTA. Factors such as intellectual property protections have been extensively analysed and are being negotiated as an important policy dimension under the AfCFTA. Other factors such as regulatory requirements for assessment of safety, efficacy, and quality of medicines and rules applying to regulatory practices, cooperation and coherence are being dealt with under the AMRH/AMA initiative. Factors such as provisions with implications for regulation of pharmaceutical marketing, rules applying to state-owned enterprises and designated monopolies, reimbursement programmes are more technical in nature and were excluded from this analysis. Other factors such as pharmaceutical pricing in the context of local manufacturing, reduction /elimination of tariffs on medicines or their ingredients, rules applying to government procurement of pharmaceuticals should be considered more carefully.

4.2.1 Intra-African trade in pharmaceuticals

Intra-African trade levels of pharmaceutical products are low, as is the case for most other sectors (Asiedu, 2021). The impact of trade and investment agreements on pharmaceutical policy has been studied, highlighting policy provisions that can influence pharmaceutical policy and practice. Strengthening the pharmaceutical system and leveraging trade agreements such as the AfCFTA are crucial to improving intra-African trade levels in pharmaceuticals.

Comparative advantage and intra-industry trade in the pharmaceutical industry can provide insights into understanding intra-African trade dynamics (Yusefzadeh et al., 2015). Various other factors, including institutional quality, trade agreements and local manufacturing initiatives, can also influence these dynamics. Institutional quality and infrastructure have been identified as factors that enhance efficiencies in intra-African trade flows (Curran et al., 2019; Yushi & Borojo, 2019).

Africa's global exports of pharmaceutical products have risen significantly from 492million USD in 2012 to 1.5billion in 2022 USD, reflecting a compound annual growth rate (CAGR) of 12%. Intra-African exports grew at a much lower CAGR of 5%, translating to a rise from 376million USD to 608million USD. As a result, intra-African exports as a share of the continent's global exports have been in a declining phase, plummeting from 76% in 2012 to 41% in 2022, as illustrated in Figure 1.

Although most of the export destinations of the top ten exporters are African countries, those of the top four exporting countries (i.e., South Africa, Arab Republic of Egypt, Morocco, and Tunisia) are destined for non-African countries, notably, Belgium, France, Saudi Arabia, and the USA, which has resulted in the fall in intra-African share of global exports.

As illustrated in Figure 2, despite a rise in intra-African pharmaceutical imports from 313million USD in 2012 to 738 million USD in 2022, the share of the global imports (i.e., including imports from non-African countries), has remained relatively flat at about 5%. Reflecting the fact that the leading importers in the continent – i.e., Arab Republic of Egypt, South Africa, Nigeria, and Morocco, source their pharmaceutical products from non-African countries like Switzerland, Germany, India, and the USA.

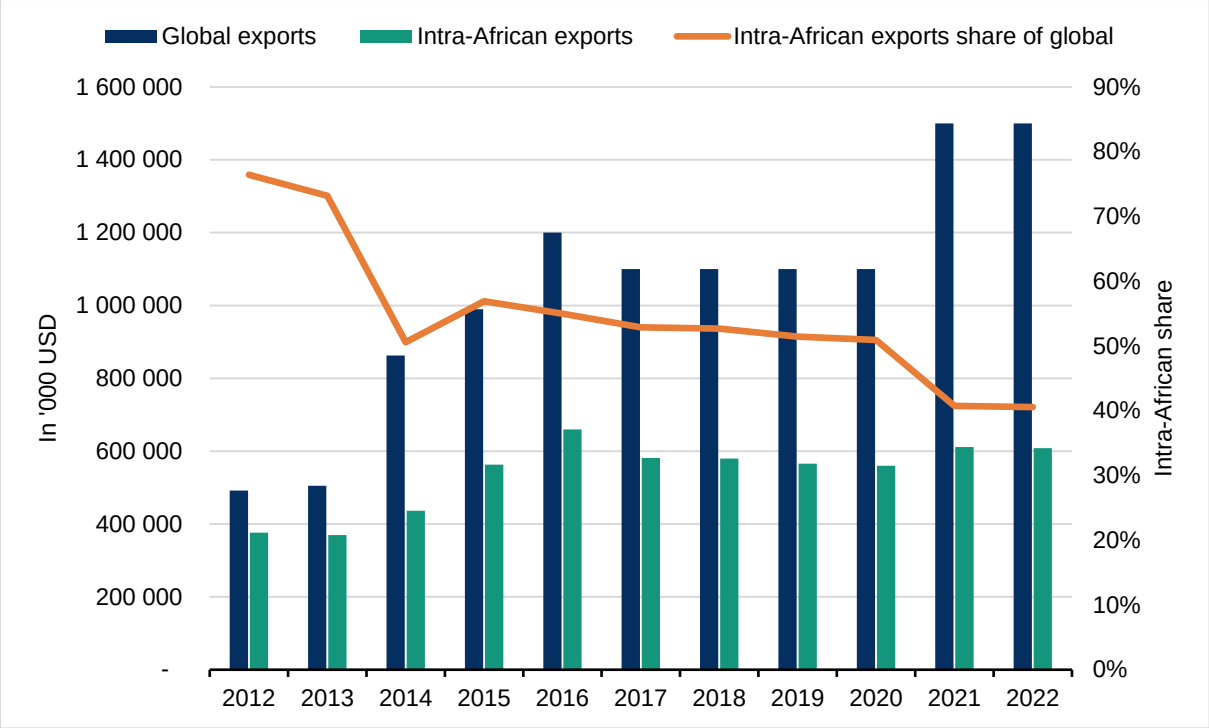

Figure 1: Africa's pharmaceutical exports (value in 1,000 USD)

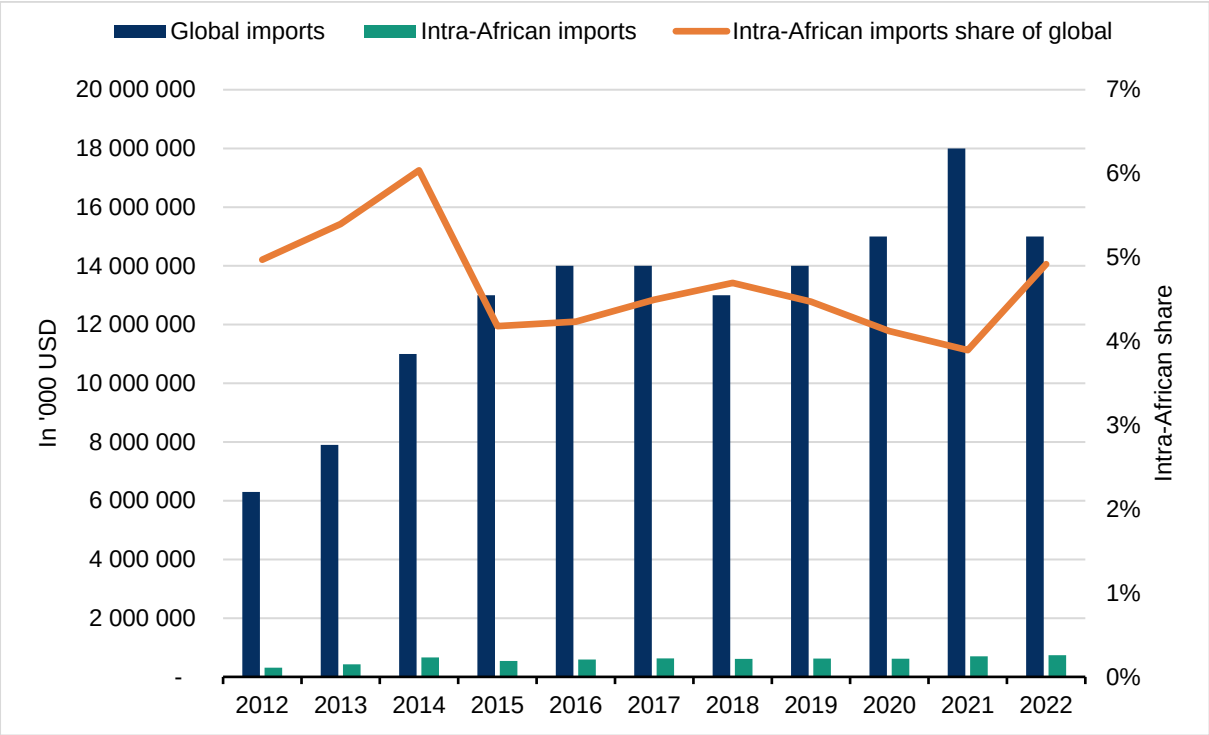

Figure 2: Africa's pharmaceutical imports (value in 1,000 USD)

Source: Analysis based on data from World Integrated Trade Solution (WITS), World Bank (2024).

Data presented in Figures 1 and 2 illustrate the low levels of intra-African exports and imports. This data is further evidence of the complex operating environment due to compliance requirements to multiple regulatory regimes across the value chain, which make it difficult for companies to supply medicines to multiple markets. The AfCFTA aims to eliminate import duties and reduce non-tariff barriers significantly. Thus, improving trade procedures through enhanced trade facilitation should reduce bottlenecks associated with intra-African trade (Asiedu, 2021).

4.2.2 Logistics and distribution

Prior to the implementation of the AfCFTA agreement and the COVID-19 pandemic, research showed that most African enterprises considered customs and trade regulations as a major constraint to trade at 40% higher in Africa than in the rest of the world. Long lead times in international procurement, fragile logistics and storage capacity, and high transport and distribution costs hinder the broad access and affordability of essential medicines (Dong & Mirza, 2016).

Porous borders, which allow the influx of parallel-traded medicines, substandard and falsified medicines into African markets, remain a major concern for companies operating legitimately in the sector and more importantly because of their dire public health consequences on populations. Pharmaceuticals require specific controls to ensure that only medicines that meet requirements of safety, quality and efficacy enter markets.

According to Gleeson et al. (2019), procedural requirements for customs administration and trade facilitation are key to improving trade in pharmaceuticals. At present, harmonisation of regulations and requirements are narrowly focused on medicines regulation, including manufacturing controls, marketing authorisation and safety vigilance and do not consider statutory controls in the rest of the value chain, which fall within the ambit of regulatory agencies involved in trade.

4.2.3 Access to finance

Positive policy developments in terms of the implementation of the AfCFTA and regulatory harmonisation should improve market attractiveness for investment in the sector. However, recent data has shown that there is an increasing trend of multinational pharmaceutical companies divesting from African markets for various reasons, including difficult operating environments, tax regimes, complexity in repatriating profits. In addition, pharma company strategies which focus more on high-margin, rare-disease medicines with smaller, niche patient populations do not bode well for pharmaceutical investment in Africa.

Despite this trend of multinational pharmaceutical company divestment from African markets, early results are showing increasing investment from local players, which is positive. Nigeria, in particular, has recently announced the approval of applications for construction of 105 manufacturing facilities for medicines across the country (EARAPA, 2024; Uzor 2023). However, to fully leverage these opportunities to create a sustainable pharmaceutical manufacturing sector (not only in Nigeria, but also the rest of the continent), requires access to finance.

Easy and sustainable access to finance mechanisms remain challenging for the setting up of new facilities and the upgrading of existing facilities. Financing for the importation of manufacturing equipment and production inputs, which are subject to exchange rate volatility, as well as high transportation costs add to overall costs of production and set-up (Banda, 2023; Uzor, 2023).

Russo and Banda (2015) emphasised the importance of economic development, government support and international funding in encouraging local pharmaceutical production in Africa (Bello & Mustapha, 2021). Despite doubts about short-term profitability, factors like improving

industrial conditions and increased international funding are tipping the balance in favour of local manufacturing (Russo & Banda, 2015).

Financial incentives by governments to support local pharmaceutical manufacturing have yielded mixed results. In South Africa, for example, despite incentives provided by the government, locally manufactured medicines still encountered competitive challenges with imported medicines as well as access to market challenges through local procurement mechanisms. This scenario is not unique to South Africa (Crouth, 2023; Horner, 2022).

Investment protections, including investor-state dispute settlement mechanisms, will be important to ensure sustainability of investments in the sector. Viability of fledgling domestic pharmaceutical industries may be reduced if government and hospital purchasing cannot preference local suppliers. Procurement mechanisms need to provide for buying from local manufacturers even though they may be priced at a premium due to local operating conditions.

4.2.4 Regional value chain development

Globalised pharmaceutical value chains have resulted in cost efficiencies but also significant consolidation and concentration of production in specific geographic locations, resulting in many markets becoming import dependent. China and to a lesser extent India, have posed a significant challenge for new and existing industries elsewhere, and especially in the Global South. This changes the prospects of economic development through local manufacturing (Horner, 2022).Formatting...

The AfCFTA calls for the development of regional value chains, including in the pharmaceutical sector, which has been identified as a priority sector for improved trade, economic growth and public health. Regional organisations are better positioned to link regional trade to region-wide health, education, social protection, and other public goods policies. In the pharmaceutical sector, regional economic communities (RECs) are already cooperating to harmonise regulations for medicines and other healthcare products with significant progress made towards a continental regulatory regime. However, this level of cooperation has not yet extended to more practical aspects of the pharmaceutical value chain.

The vision of regional value chains in the pharmaceutical sector has not been defined. Such a vision would need to consider the specific capabilities of countries as well as private sector actors' willingness to cooperate and do business with counterparts in other countries in Africa to improve the efficiencies and competitiveness of pharmaceutical value chains. It is unlikely that a 'one-size-fits-all' approach would suffice, as different types of medicines would require different manufacturing approaches. Intra-regional trade and investment linkages need to be analytically understood and empirically examined to make regional cooperation initiatives development oriented (Asiedu, 2021; Yusefzadeh et al., 2015).

Countries with more advanced manufacturing capabilities hold potential for Africa's growth, and a reduction in imports if such countries in Africa can access the larger African market – the AfCFTA creates the platform for such opportunities to be leveraged. Despite the need for stronger economic cooperation in developing countries, there are very few regional economic integrations in the developing world, compared to many successful economic groupings found in the developed world (Asiedu, 2021).

Membership of countries to multiple RECs have seemingly exacerbated the slow progress of inter-regional integration on the African continent. Thus, even though there are benefits to sub-regional bloc integration (i.e., Economic Community of West African States (ECOWAS), East African Community (EAC), Southern African Development Community (SADC), and Arab Maghreb Union (AMU)) a continental trade bloc, such as is proposed by the African Continental Free Trade Agreement (AfCFTA) would be beneficial in increasing intra-African trade (Asiedu, 2021).

The launch of the AfCFTA in early 2021 provides a unique opportunity to leverage capabilities and synergies across markets to enhance and optimise pharmaceutical sector growth and competitiveness through the development of regional value chains.

5 Policy recommendations

The policy interventions that promote local pharmaceutical manufacturing are predominantly developed at a regional or supranational level, leaving individual markets to figure out how these policies will be implemented and institutionalised at a local level in the context of existing policies and laws. This creates significant policy implementation complexity and relies on significant levels of local political will and resource allocation for policy implementation. Challenges persist in financing innovation, industrial development, and building institutional and regulatory capacity for emerging technologies (Banda, 2023).

Policy cohesion, predictability and transparency are critical to growth and further development of the pharmaceutical sector in Africa. This would require collaboration and alignment across different arms of government at a continental, national and regional level, with consideration of public health and industrial development objectives and interests. Based on the analysis of key factors that affect pharmaceutical trade and manufacturing, strategic policy choices need to be made on the key areas of focus based on level of importance, feasibility and potential impact on the creation of regional value chains in the healthcare sector.

Understanding the dynamics of globalised pharmaceutical value chains will be important to identify competitive and operational challenges that local manufacturers face, as well as to determine policy interventions required to support growth in the local pharmaceutical manufacturing sector (Horner, 2022). The following sections offer policy recommendations based on this study's analysis.

5.1 Clearly define regional integration and regional value chains

The AfCFTA calls for the development of regional value chains; however, the structure and nature of these regional value chains have not been defined. It is therefore unclear whether the establishment of regional value chains requires policy intervention or determination by the private sector and market forces. Policymakers across Africa would like to see local manufacturing in their own markets, but this would lead to duplication of effort with high opportunity costs of efficiencies through economies of scale and lack of competitiveness both in Africa and beyond. Focus should be given to comparative advantages of individual countries to establish regional value chains to leverage individual strengths to optimise regional value chains.

Allied and associated industries that will support the local pharmaceutical manufacturing value chain are necessary and important. Therefore, further opportunities for non-manufacturing markets exist to participate and contribute towards supporting the growth of local pharmaceutical manufacturing. These related opportunities could include packaging materials, equipment maintenance, waste management, and regulatory and information technology support services. Leveraging these opportunities can also lead to further job creation and economic development. Consequently, effective regional partnership strategies are required to create borderless regional pharmaceutical industries to become new competitive operational entities on the African continent (Dong & Mirza, 2016).

5.2 Establish private-private partnerships for API & excipient manufacturing

It is well known that API manufacturing requires specialised skills and advanced technologies. However, this is also a moving target as pharmaceutical R&D continuously brings new innovations to market and innovation moves more in the direction of biological and personalised medicine. Consequently, API manufacturing capabilities need to be future-proofed and agile to adapt to innovation.

As with finished product manufacturing, API manufacturing also requires starting materials and intermediates as key production inputs. The value chain has been largely consolidated with only a few markets globally involved in API manufacturing, which creates risk in terms of security of supply as was seen during the pandemic. Opportunities to produce starting materials and intermediates, which require slightly lower levels of technological capacity, should be explored to further diversify the global value chain for API manufacturing. In addition, continuous manufacturing processes which reduce production down time should be explored further (Aulakh et al., 2022, Poechlauer et al., 2012).

To circumvent the lag time and resources required to become competitive in this space, partnership opportunities should be explored to leverage the expertise and potential investment of international players that have experience in manufacturing these production inputs competitively. The potential benefits to these international players will be diversification of their supply chains and access to new markets in Africa.

5.3 Improve institutional capacity for intra-Africa trade of pharmaceuticals

Trade policy includes a wide range of government regulations which affect the capacity of suppliers to access markets, including standards for product safety, sanitary and phytosanitary measures, intellectual property rights and technical barriers to trade. To ensure sufficient regulatory oversight, operational efficiencies as well as transparency and governance, institutions responsible for these activities need to be sufficiently capable and well resourced (Curran et al., 2019).

Institutional capacity is important for policy implementation and institutions are also targets for policy intervention. Current institutional capacity development has been focused on improving regulatory capacity, manufacturing processes and to a lesser extent on R&D. Therefore, a more comprehensive approach is required for institutional capacity development across the pharmaceutical value chain (Banda, 2023).

Issues such as parallel trade, influx of substandard and falsified medicines remain a public health and economic threat. With the implementation of the AfCFTA, institutions will promote free trade of goods and services across borders, including medicines. The associated risks are that problems associated with parallel trade, counterfeit and falsified medicines could be further exacerbated if institutions responsible for customs and border control are not adequately capacitated to deal with potentially increasing intra-African trade levels. Training in the correct identification of legitimate pharmaceutical products will also be required.

Medicines need to be stored and transported with due consideration of temperature controls to ensure that the safety, quality and efficacy of products remain intact. Customs and border controls need to operate in such a way to ensure safe and efficient delivery of legitimate medicines in the shortest possible time without compromising product integrity.

5.4 Address tariff and non-tariff barriers to pharmaceutical trade

There is a multitude of regulatory regimes that companies need to navigate for the supply of medicines across borders. Several country-specific regulatory requirements are contained in national legislation and increase levels of complexity for companies to navigate and comply. Current regulatory harmonisation initiatives do not address these requirements (such as labelling information and language requirements) that can become non-tariff barriers that hinder the supply of medicines to multiple markets. Local legal reform is required that aligns with continental requirements that are being developed and/or supranational legislation and agreements that will supersede national requirements (Narsai et al., 2024).

For local pharmaceutical manufacturing to thrive, tariff barriers related to the import of production inputs need to be addressed. These tariffs are not necessarily applicable to finished products that are imported but are applicable to production inputs that are used in the manufacturing process. These tariffs have multiple impacts on the overall cost of production as well as the overall competitiveness of locally produced medicines in that they need to compete with lower cost imports that do not attract similar tariffs. It is recommended that tariffs on production inputs be reduced or waived to support growth in local pharmaceutical manufacturing.

5.5 Improve market access

Policy recommendations for market access can be viewed from two main perspectives: (i) In setting up and increasing local pharmaceutical manufacturing footprints in Africa; and (ii) Access to markets through procurement mechanisms, which will not only have direct impacts on local manufacturing levels, but also on the sustainability of local manufacturing.

From the data reviewed, financial incentives alone have not resulted in increased levels of local pharmaceutical manufacturing. However, access to finance is still cited as a barrier to entry into local pharmaceutical manufacturing due to the high levels of capital investment required and complexity of pharmaceutical manufacturing. It is fair to assume that manufacturing complexity will increase due to new types of products emerging from R&D pipelines (Abbot et al., 2021; Sarkis, 2021).

Banks, funders and investors play a critical role in the development of new markets, industries and economic growth. Processes related to mobilising savings, project evaluation, risk management, monitoring and facilitating transactions are important to economic development and operationalising businesses (Banda, 2023). In addition to this, non-financial support such as technical assistance and mentorship are required for local manufacturers to attain the necessary technical acumen required for sustainability. Policymakers should also look at comprehensive incentive schemes that consider cost minimisation across the value chain, such as incentives for capital investments, preferential access to water and electricity, import tariff regimes and customs and border controls.

The state as the largest procurer of medicines in many markets in Africa has a significant role to play in creating preferential procurement mechanisms that prioritise local manufacturers. This would require coordination amongst government departments to ease the tensions between industrial and health policy objectives. Public procurement of medicines is predominantly driven by public health interests – these will need to be balanced by the need to grow the local pharmaceutical manufacturing sector by ensuring predictable demand that will aid production planning and ensure business sustainability. More recently, pooled procurement mechanisms have gained momentum across the continent through the African Pooled Procurement Mechanism (APPM), which has been established by the Africa Centre for Disease Control and Prevention (Africa CDC) and seeks to be operational within the next three to five years (Maeko, 2024). Operationalising such a mechanism needs to consider

alignment with existing procurement mechanisms and national procurement regulations which are already enforced in individual markets in Africa. Due consideration should be given to the impact of procurement on the growth and sustainability of local pharmaceutical manufacturers.

5.6 Fast track regulatory harmonisation implementation

There has been a plethora of reports, publications, conferences and dialogues on regulatory harmonisation that continue to drive the momentum of the establishment of the African Medicines Agency (AMA). Regional initiatives are also gaining ground in terms of the implementation of joint review processes and work-sharing models (Miletic et al., 2023). The impact of these initiatives in terms of real investment in the sector as well as reducing complexities for both local and multinational pharmaceutical companies is still illusive due to national medicines legislative frameworks that are still enforced. What is required is national legal reform of medicines legislation to accommodate regulatory harmonisation efforts to avoid increasing compliance costs and complexity for players in the sector.

5.7 Expand regulatory harmonisation approach to include value chain

At present, regulatory harmonisation efforts are narrowly focused on medicines regulation in terms of safety, quality and efficacy. However, there are other agencies and government departments involved in regulating other parts of the pharmaceutical value chain (such as port authorities, customs agencies, non-medicine regulators of standards). Coordination, collaboration and alignment of standards across agencies and government departments will be critical to value chain optimisation. Therefore, a broader approach to regulatory harmonisation needs to be taken by policymakers across the continent that consider the broader objectives of free trade under the AfCFTA, local production, pooled procurement and health systems delivery mechanisms.

6 Conclusion

This landscape analysis revealed that several countries are making good progress in establishing pharmaceutical manufacturing, which include Nigeria, South Africa, Ethiopia and Kenya. Other emerging manufacturing countries include Senegal, Morocco and Rwanda (Ndomondo-Sigonda et al., 2017; Okereke et al., 2022; Ussai et al., 2022).

This emphasises the need for further investment in manufacturing infrastructure, allied industries, as well as research and development of infrastructure to address current and emerging public health needs. Interventions related to healthcare delivery infrastructure, procurement, regulatory oversight in terms of logistics and supply chain, import and export rules and tariffs, and patient acceptance of products, amongst other factors also need to be addressed. Several international development organisations continue to support initiatives and projects related to pharmaceutical value chain development, particularly those initiatives that are focused on local manufacturing of antiretrovirals and more recently, vaccines. These opportunities and resources should be further leveraged to broaden the manufacturing base in a sustainable way. The impact of market access considerations, specifically those that offer local manufacturers access to procurement mechanisms, cannot be underestimated – pooled procurement mechanisms which seek to address this challenge should be prioritised.

The pharmaceutical manufacturing sector in Africa is evolving. While challenges exist, there is growing momentum to strengthen local pharmaceutical manufacturing capacity, improve regulatory oversight and address the impact of global health crises. Balancing objectives of health and trade policy should remain a priority for policymakers. If challenges related to pharmaceutical manufacturing and trade are appropriately and adequately addressed, then the full potential of the sector to meet trade and public health objectives will be realised.

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Appendix A: Quantitative Analysis Results

A mapping of the pharmaceutical manufacturing sector across Africa, including specific skills and capabilities of countries, both contributors and non-contributors (for pharmaceuticals, vaccines and specific medical devices) is required. This would require original research to be conducted in the area. It will inform recommendations to leverage existing manufacturing infrastructure that may not be currently utilised or is being under-utilised and reveal immediate opportunities in local manufacturing of medical consumables to support pharmaceutical and vaccine value chains.

Table 1: Top 10 exporters of pharmaceuticals (2022)

Country	Exports (value in $1000's)	Share of total exports	Top three export destinations	Leading export products
South Africa	723,941.00	49.71%	Belgium, Namibia, Botswana	Human blood animal blood preparations, medicaments
Arab Republic of Egypt	319,281.00	21.92%	Saudi Arabia, Yemen, Sudan	Medicaments, wadding, gauze, bandages & similar articles
Morocco	129,330.00	8.88%	France, Mauritania, Libya	Medicaments, wadding, gauze, bandages & similar articles
Tunisia	107,259.00	7.36%	France, Libya, Saudi Arabia	Medicaments, pharmaceutical goods specified
Kenya	104,809.00	7.20%	Tanzania, Uganda, Malawi	Medicaments, human blood animal blood preparations
Botswana	21,275.60	1.46%	Zambia, Namibia, Zimbabwe	Human blood animal blood preparations, medicaments
Mauritius	18,807.30	1.29%	Belgium, Other Asia, United States of America (USA)	Human blood animal blood preparations, medicaments
Cote d'Ivoire	7,312.72	0.50%	Mali, France, Burkina Faso	Medicaments, pharmaceutical goods specified
Benin	4,500.52	0.31%	Togo, Guinea, Burkina Faso	Medicaments, human blood animal blood preparations
Zimbabwe	3,374.27	0.23%	Botswana, Namibia, South Africa	Medicaments, pharmaceutical goods specified

Source: Analysis based on data from WITS, World Bank (2024).

Table 2: Top 10 importers of pharmaceuticals (2022)

Country	Imports (value in $1000's)	Share of total imports	Top three import origins	Leading import products
Arab Republic of Egypt	3,500,000.00	22.94%	Switzerland, Germany, USA	Medicaments, human blood animal blood preparations
South Africa	2,500,000.00	16.39%	India, Germany, USA	Medicaments, human blood animal blood preparations
Nigeria	1,100,000.00	7.21%	India, China, Malaysia	Medicaments, human blood animal blood preparations
Morocco	827,053.00	5.42%	France, Germany, India	Medicaments, human blood animal blood preparations
Ethiopia	787,533.00	5.16%	India, Belgium, Netherlands	Medicaments, human blood animal blood preparations
Kenya	764,974.00	5.01%	India, USA, Germany	Medicaments, human blood animal blood preparations
Tanzania	750,136.00	4.92%	India, Belgium, Netherlands	Medicaments, human blood animal blood preparations
Angola	678,248.00	4.45%	India, Portugal, Netherlands	Medicaments, human blood animal blood preparations
Tunisia	568,357.00	3.73%	France, Germany, Italy	Medicaments, human blood animal blood preparations
Cote d'Ivoire	481,674.00	3.16%	France, India, China	Medicaments, human blood animal blood preparations

Source: Analysis based on data from WITS, World Bank (2024).

Table 3: Top 10 countries exporting pharmaceuticals within Africa (2022)

Country	Exports (value in $1000's)	Share of total exports	Top three destinations	Leading export products
South Africa	306,115.00	50.31%	Namibia, Botswana, Eswatini	Medicaments, human blood animal blood preparations
Kenya	100,789.00	16.57%	Tanzania, Uganda, Malawi	Medicaments, human blood animal blood preparations
Arab Republic of Egypt	90,964.50	14.95%	Sudan, Libya, Tanzania	Medicaments, wadding, gauze, bandages and similar articles
Tunisia	32,200.30	5.29%	Libya, Cote d'Ivoire, Algeria	Medicaments, wadding, gauze, bandages and similar articles
Morocco	30,302.60	4.98%	Mauritania, Libya, Senegal	Medicaments, human blood animal blood preparations
Botswana	21,225.30	3.49%	Zambia, Namibia, Zimbabwe	Human blood animal blood preparations, medicaments
Cote d'Ivoire	4,949.64	0.81%	Mali, Burkina Faso, Senegal	Medicaments, pharmaceutical goods specified
Benin	4,449.88	0.73%	Togo, Guinea, Burkina Faso	Medicaments, human blood animal blood preparations
Zimbabwe	3,369.39	0.55%	Botswana, Namibia, South Africa	Medicaments, pharmaceutical goods specified
Togo	3,283.06	0.54%	Benin, Burkina Faso, Mali	Medicaments, wadding, gauze, bandages and similar articles

Source: Analysis based on data from WITS, World Bank (2024).

Table 4: Top 10 countries importing pharmaceuticals within Africa (2022)

Country	Imports (value in 1000usd)	Share of total imports	Top three import origins	Leading import products
Zambia	250,551.00	33.95%	Equatorial Guinea, South Africa, Botswana	Medicaments, human blood animal blood preparations
Namibia	74,892.60	10.15%	South Africa, Botswana, Zimbabwe	Medicaments, human blood animal blood preparations
Zimbabwe	73,594.90	9.97%	South Africa, Mauritius, Kenya	Medicaments, human blood animal blood preparations
Botswana	58,867.30	7.98%	South Africa, Zimbabwe, Kenya	Medicaments, human blood animal blood preparations
Tanzania	48,658.20	6.59%	Kenya, Arab Republic of Egypt, Uganda	Medicaments, human blood animal blood preparations
Cote d'Ivoire	26,131.40	3.54%	Morocco, Tunisia, Ghana	Medicaments, human blood animal blood preparations
Mozambique	22,958.20	3.11%	South Africa, Kenya, Uganda	Medicaments, human blood animal blood preparations
Kenya	16,304.20	2.21%	South Africa, Uganda, Arab Republic of Egypt	Medicaments, human blood animal blood preparations
Burkina Faso	15,869.00	2.15%	Ghana, Mali, Morocco	Medicaments, human blood animal blood preparations
South Africa	14,459.40	1.96%	Uganda, Botswana, Arab Republic of Egypt	Medicaments, human blood animal blood preparations

Source: Analysis based on data from WITS, World Bank (2024).

Appendix B: Background review of quantitative evidence of the African pharmaceutical industry, trade flows and trade barriers

Summary

Africa's pharmaceutical production through some 600 to 1000 manufacturers covers 3% of global production. Some 80% of local production is undertaken in eight African countries. Africa imports some 80% of what it consumes. African countries including those with some capacity have a negative trade balance in pharmaceutical trade. Tariff and non-tariff barriers to African trade are significant.

Pharmaceutical production

The size of Africa's pharmaceutical market, estimated at between $40 billion and $60 billion, pales in comparison to that of the USA, which is still the largest pharmaceutical market in the world (estimated at $393 billion) (Conway et al, 2019) or many other major countries. Production by Africa's pharmaceutical industry is very low and the demand for health products in Africa far supersedes the current manufacturing capacity and capabilities.

The industry's small size results from a multitude of factors including market access, technical capacity challenges, regulatory challenges, leading to a small number of firms operating in a concentrated number of countries. As of 2020, there were approximately 600 to 1,000 pharmaceutical manufacturers in Africa across 20 countries, with eight countries (Arab Republic of Egypt, Algeria, Morocco, Tunisia, Nigeria, Ghana, Kenya, and South Africa, accounting for 80% of local production (see Figure 3) (Conway et al, 2019; Ussai et al., 2022). More specifically, only four countries have more than 50 pharmaceutical manufacturers. The number of manufacturers is significantly lower than in India (5,000) and China (10,500) (Development Reimagined, 2022; Ussai et al., 2022).

There is a significant disparity between market demand and local manufacturing capacity with Africa accounting for only 3% of global pharmaceutical manufacturing. The continent is highly dependent on imported pharmaceutical products as it imports more than 80% of the pharmaceutical products it consumes. Imports are mainly from the European Union (51.5%), India (19.3%), Switzerland (7.7%), China (5.2%), United States of America (4.3%), and the United Kingdom (3.3%) (Development Reimagined, 2022; Ussai et al., 2022).

Expanding pharmaceutical manufacturing to areas with little or no manufacturing activity is challenging due to high barriers to entry caused by stringent regulations and significant levels of capital investment to get started. In addition, regulatory barriers, access to skilled labour, challenges to economies of scale and due to market fragmentation. Despite these challenges, the last few years have shown significant investment through local and international investors in local pharmaceutical manufacturing capacity.

Issues hampering intra-African trade levels such as market fragmentation due to multitudes of regulatory regimes across markets remain a significant barrier. The AfCFTA provides a platform and opportunities to address these barriers and improve intra-African trade levels. (Signé & Munyati, 2023)

Figure 3: Pharmaceutical production in Africa is low and heavily concentrated

Source: Asoko Insight (2023).

Pharmaceutical trade in Africa

An analysis of trade data shows that most African countries have a trade deficit in pharmaceutical trade (using export values data for 2022). Even countries such as South Africa and the Arab Republic of Egypt with solid pharmaceutical manufacturing capacities, have record deficits of more than US $2 billion (Figure 4).

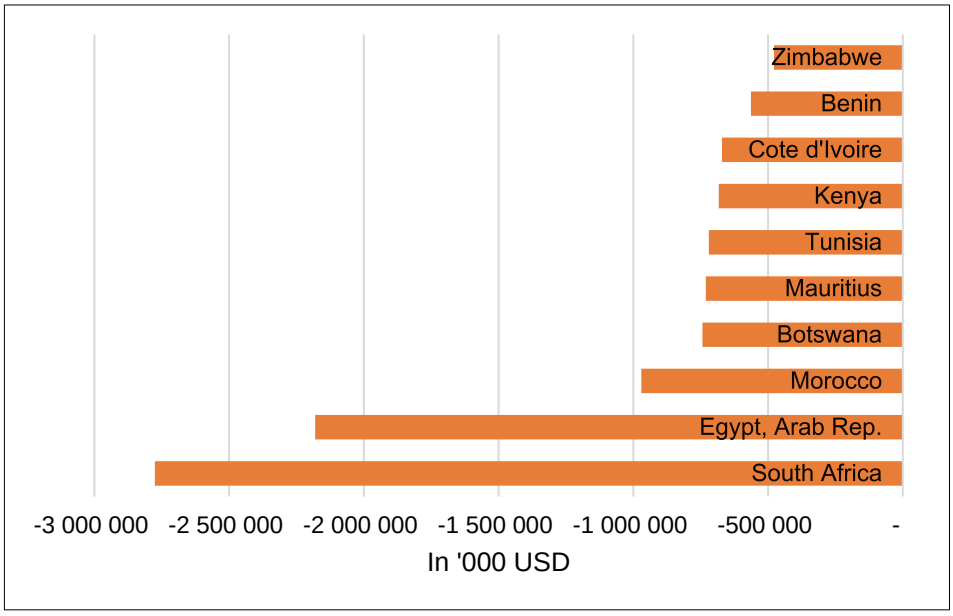

Figure 4: Trade balance in pharmaceuticals (in 1,000 USD) of selected African countries (2022)

Source: Own calculations using data from WITS, World Bank (2024).

Hakobyan and Cherif (2021) argued that intra-regional trade in medical goods[2] covers 10% of medical imports for sub-Saharan Africa but can be up to 70% in Namibia and Swaziland.

[2] They define medical goods using the World Trade Organization/World Customs Organization (WTO-WCO) and World Bank classifications of COVID-19-related medical supplies and include 154 products at the HS 6-digit level.

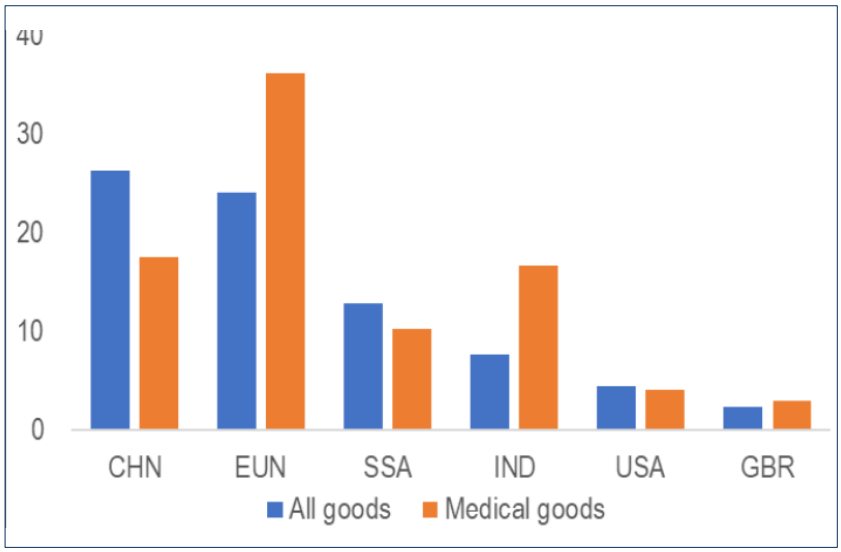

Figure 5: Top source countries for sub-Saharan Africa imports (2019)

Source: Hakobyan and Cherif (2021, p.2).

Tariffs and non-tariff barriers to pharmaceutical trade in Africa

Part of the reason for weak manufacturing production and trade of pharmaceutical products in Africa may be due to high tariff and non-tariff barriers. The average most-favoured-nation (MFN) tariff rates applied on pharmaceutical products stand at 10% in Africa compared with 2.9% in advanced countries (European Commission, 2022; Karaki & Ahairwe, 2022) These tariff rates increase the prices of finished products and inputs for value-added manufacturing in the continent. For specific pharmaceutical products, African countries are notable for having much higher average tariff rates.

Analysis of tariffs data sourced from the World Bank's World Integrated Trade Solutions (WITS) (2024) revealed that MFN tariff rates could reach a high of 30% (for medicaments), 25% (for wadding, gauze, bandages and similar articles), 25% (for first-aid boxes and kits), and 23% (for dental cements and other dental fillings). Intra-REC tariffs will be lower, but AfCFTA still has significant scope to reduce inter-REC tariff rates.

Hakobyan and Cherif (2021) suggested that sub-Saharan Africa has higher MFN tariff rates on medical goods (9.2%) compared to advanced economies (1.9%) and other emerging market and developing economies (6.6%). The highest import tariffs are on PPE and soap and the lowest tariffs are on goods without significant local production capacity (test kits, medical devices, etc). African countries offer preferential tariff rates (33 out of 45 SSA countries), but the average preference is just 0.2%, compared to the average MFN tariff rate of 15%. Since the average bound tariffs on medical goods are five times higher than applied tariffs, this makes the trade environment uncertain.

Navigating multiple regulatory regimes can be challenging for pharmaceutical companies that are seeking market entry in multiple markets in Africa. The cost of compliance to these multiple regulatory regimes proves to be a barrier to entry. In addition, other factors, such as currency fluctuations, operational complexities, lack of return on investment, hamper market attractiveness for pharmaceutical companies. This has led to major pharmaceutical players exiting from African countries.

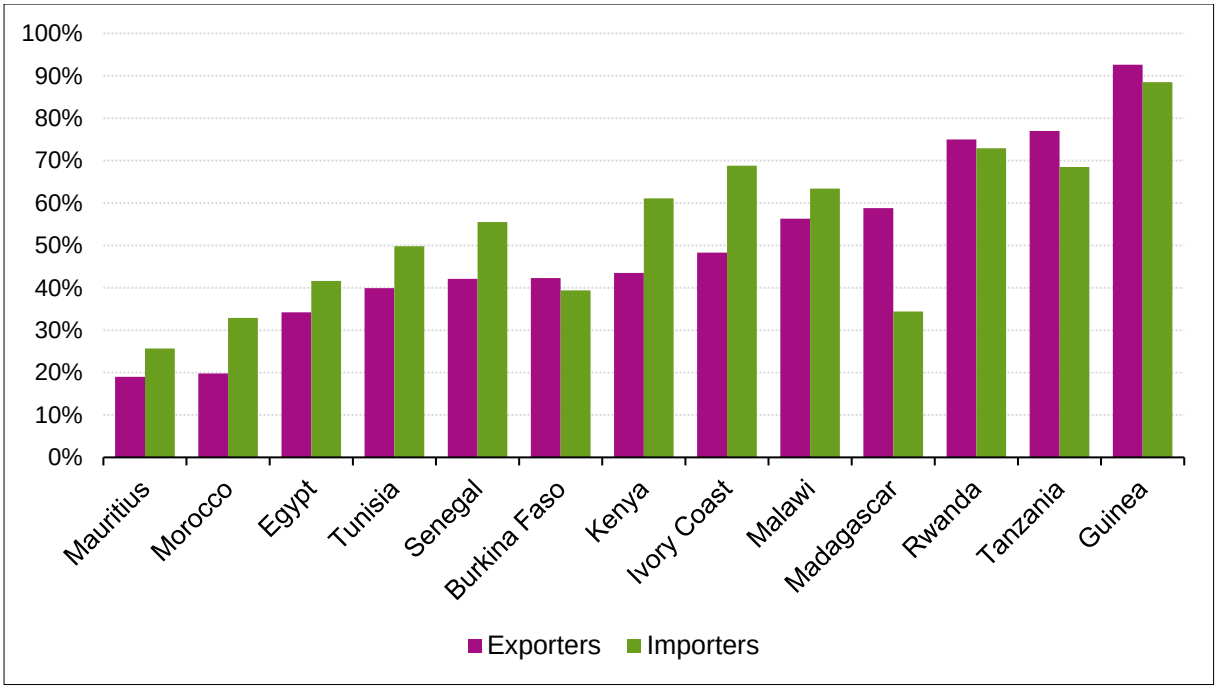

Figure 6: Survey responses from African manufacturing firms on non-tariff barriers to trade

Source: Own elaborations using data from ITC (International Trade Centre, 2022).

Apart from high tariff rates, non-tariff measures (NTMs) make it difficult for companies to trade pharmaceutical products in Africa. Examples of NTMs include rules of origins and related certificate of origin, charges, levies and taxes, conformity assessment, and pre-shipment inspection. As shown in Figure 6, analysis survey responses of manufacturing companies (which include pharmaceutical firms), show that NTMs significantly hamper both exports and imports of manufactured products, with barriers to imports the severest (International Trade Centre, 2022). With limited continental manufacturing of critical pharmaceutical inputs, notably, APIs, punitive NTMs on imports can pose a challenge to expanding manufacturing.

Specifically in the pharmaceutical sector, survey responses reveal that 80% of pharmaceutical companies face obstacles when exporting to African markets and about 60% face trade obstacles when importing inputs from another African country. The time, cost and bureaucracy that is associated with product registrations, which varies across countries, are the chief reasons reported by companies for difficulty in intra-African trading of pharmaceutical products (International Trade Centre, 2022). For instance, survey results from Kenyan manufacturing trading companies, reveal that “unusually high fees and charges” charged by the Kenyan Pharmacy and Poison Board is one of the procedural obstacles encountered when processing exports (European Commission, 2022). Such fees, according to the survey results, are charged on certification, permits or licences required to export, which have not been harmonised across countries, especially in East Africa.