Common Market for
Eastern and Southern Africa

Market Research to Identify and Analyze Supply and Demand Gaps in COVID-19 Related Pharmaceutical Goods and Services in the COMESA Region

Final Validated Report

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14th June, 2022

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Acronyms and Abbreviations

Africa CDC	Africa Centres for Disease Control
AcFTA	African Continental Free Trade Area
AfDB	African Development Bank
AFREXIMBANK	Africa Export Import Bank
AMA	African Medicines Agency
AMDF	African Medical Devices Forum
API	Active Pharmaceutical Ingredients
AU	African Union
AU-NEPAD	African Union New Partnership for Africa's Development
CET	Common External Tariff
COMESA	Common Market for Eastern and Southern Africa
COMTRADE	Commodity Trade Statistics Database
ITC	International Trade Centre
GAVI	Global Alliance for Vaccines Initiative
GDP	Gross Domestic Product
GMP	Global Manufacturing Practices
MOH	Ministry of Health
NMPA	National Medicines Procurement Agencies
NTBs	Non-Tariff Barriers
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPEs	Personal protective equipment
PQ	Performance Qualification
RECs	Regional Economic Communities
SWOT	Strength Weaknesses Opportunities and Threats
TOR	Terms of Reference
UNICEF	United Nations International Children's Emergency Fund
WTO TRIPS	World Trade Organisation Trade Related aspects of Intellectual Property Rights

Executive Summary

The Common Market for Eastern and Southern Africa (COMESA) is a 21 Member States' economic block with a population of over 583 million, a Gross Domestic Product of $805 billion and global export/import trade in goods worth USD 324 billion. The region aspires to create an enabling environment and legal framework which will encourage growth of the private sector, the establishment of a secure investment environment and the adoption of common sets of standards. A well-established regional pharmaceutical and medical products manufacturing that supplies lifesaving commodities, reduces dependence on imports, builds pandemic resilience and promotes industrialization has been prioritized by the region.

It is in this regard that the African Development Bank (AfDB) supported the COMESA Secretariat to carry out market research to identify and analyse supply and demand gaps in COVID-19 related pharmaceutical goods and services in the COMESA region. This report highlights the findings of the study and recommendations.

In 2020, the region imported pharmaceuticals worth USD 5.6 billion and exported USD 457 million (ITC, 2022). The intra COMESA imports were reported at USD 178 million indicating an overreliance (approx. 97 percent) of imports from outside the region (COMSTAT,2022). A similar trend was observed in other medical supplies where the imports were several times higher than the intra-regional trade and exports respectively. In addition, the total exports were more than those of intra-regional trade for all categories of products except laboratory reagents. This indicates that the region is trading more with markets outside COMESA than within herself.

On intra-regional trade in pharmaceuticals, Kenya and Egypt dominate in exporting to the other countries

in the region. The top five supplier countries in 2020 have a combined share of 87 percent demonstrating a dominance of intraregional trade by a few countries. A closer examination of export destinations from the supplier countries indicate that geographic proximity plays a key role. For example, Zimbabwe export destinations is to the neighbouring countries of Zambia, Malawi and Eswatini. Even for the leading pharmaceutical producers in the region, the same applies as shown by their export volumes, for Kenya, exports to Uganda account for 38 percent of her total exports to COMESA while for Egypt exports to Libya account for 44 percent.

The region imported USD 622 million worth of laboratory reagents in 2020 with intra-regional trade and exports being only USD 8 million and USD 4 million respectively (ITC,2022). This indicates a huge unmet demand through local production and therefore an opportunity to scale up the same. Significant opportunities exist for import substitution for syringes, needles and cannulas and to expand intra-regional trade as the intra-regional trade and exports from the region are only three percent and 13 percent of imports respectively.

Egypt, Kenya and Mauritius are the leading exporters of diagnostic reagents, needles and syringes, with the three countries having a combined share of over 80 percent of the total exports from the region. Notably, the exports to outside of COMESA for these countries are higher than the intra-regional trade. However, the absolute values are very low when compared with imports.

The steep challenge around access to COVID-19 vaccines has triggered capacity creation impetus across the continent. In the region only, Vacsera in Egypt and Pasteur Institut of Tunisia have limited volume drug substance manufacturing, fill-finish, along with packaging and distribution. However, as a result of the COVID-19 pandemic, Kenya, Rwanda and Uganda have announced plans to set up vaccine manufacturing plants. Kenya has signed a memorandum of understanding with Moderna for a USD 500 million investment in a drug substance vaccine manufacturing plant. Minapharm and BioGeneric, from Egypt through a partnership with Russian Direct Investment Fund (RDIF) intend to set up drug substance production plants for Sputnik.

The majority of pharmaceutical manufacturers in the region produce simple generic formulations instead of higher value medicinal products. Moreover, most local firms compete with each other in the same market segments as they have similar product portfolios. The market dominance of imports is partly attributed to a host of factors that disadvantages pharmaceutical manufacturing in the region. The reasons for this are varied but range from lack of capacity to produce inputs such as active pharmaceutical ingredients, high production costs and policy incoherence at the interface of health, trade and industrialization. Further, local manufacturers struggle to adhere and comply with internationally recognized Good Manufacturing Practices such as WHO GMP. Governments across the region have put in place incentive frameworks to promote local pharmaceutical production. Despite the existing incentives, local manufacturers across the region complain of being disadvantaged against imports.

An assessment of the pharmaceutical industry in the region demonstrates a nascent but a growing sector with increasing complexity. The industry varies from country to country with Egypt, Kenya and Tunisia being relatively well developed and diversified. For Egypt and Tunisia leading multinationals have set up manufacturing facilities alone or through joint ventures or contract manufacturing arrangements. The investment in a specialised pharmaceutical park in Ethiopia plus introduction of other incentives has attracted leading generic manufacturers from India and China. Mauritius is positioning herself to attract investments in biotechnology, medical devices and contract research services with a raft of incentives being put in place. Uganda has introduced a positive list to promote local production and the establishment of WHO prequalified facility in the country through a joint venture arrangement stands out.

The value chains for the other medical supplies in the region are not as developed as that of pharmaceuticals. The reasons for this include lack of access to technology and know-how; unavailability of raw materials and other support industries; and poorly developed regulatory environment which discourages investment from global players owing to reputational risk. There is limited capacity in the region to produce rapid diagnostics in the region with countries such as Kenya, Uganda, Egypt and Mauritius having packaging plants. The production of medical devices requires multi-disciplinary approach involving medical, biotechnology and engineering professionals. Across the region, there exists skills gaps and product development expertise with poor linkages between the academia and industry. As a result, the development of medical devices gets stuck at prototype stage with innovators not able to progress to commercialisation and scale up.

In order to promote investments in pharmaceuticals and medical products in the region, there is need for policy actions targeting specific sections along the value chain. The Interventions should aim at improving the framework conditions that level the playing field whilst supporting the nascent local industry and promoting regional value chains. The existing constraints that impede regional trade needs to be addressed.

The manufacturers prioritised the need to accelerate harmonisation of regulation and standards. In addition, preferential treatment should be extended by all Member States to regional manufacturers in public tenders for medical products. This will confer an advantage to regional manufacturers over imports from outside COMESA.

Further, in order to encourage the setting up of production facilities in the region there is need to review the common external tariff (CET) for medical products. For example, the CET for selected products which the region has capacity to produce in sufficient quantity and acceptable quality should be increased from the current zero percent to a higher figure. Access to appropriate financing for the manufacture of medical products should be promoted by encouraging financial institutions to develop special packages that recognise the unique characteristics of the sector. For diagnostics and medical devices, a regional approach should be taken to promote research and development, innovation and commercialisation.

Some of the policy actions for implementation at the national level include developing and implementing incentives for the manufacture of finished products, active pharmaceutical ingredients (APIs) and other medical products. Each of these products would require a unique set of incentives. For example, the production of APIs presents a greater business risk than finished products, therefore the incentives should take this into consideration through granting of tax breaks. The Member States should put in place policies that promote investments in herbal and medicinal products targeting agronomic practices, collection and aggregation, regulation and processing.

The region is at nascency stage in the production of diagnostics and medical devices. Therefore, policy actions should be geared towards promoting research and development (R&D), innovation, incubation and commercialisation as development of prerequisite skills mix. In order for vaccine production to be viable in the region, there is need for advance market commitments by the host government and other Member States as well operationalising regional pooled procurement.

The region should promote the establishment of specialised pharmaceuticals and medical products parks. The specialised parks will provide shared infrastructure including reliable supply of utilities and delivery of government services through a one-stop shop concept. These initiatives are likely to attract investments as it lowers the initial capital outlays. At firm level, companies will need to match their product portfolio with the regional needs and must be competitive with regards to quality, functionality and price

amongst other parameters.

The following recommendations are proposed for action at regional and national level;

- Establish a sustainable regional coordination mechanism on promotion of medical products manufacture;
- Strengthen access and exchange of reliable market information;
- Promote regional harmonisation of medical products regulation and standards;
- Promote market shaping and consolidation in the region;
- Improve access to appropriate financing;
- Promote partnerships and investments in provision of industry support services;
- Promote linkages and development of regional value chains.

1 Background and Introduction

The Common Market for Eastern and Southern Africa (COMESA) is a 21 Member States' economic block with a population of over 583 million, a Gross Domestic Product of USD 805 billion and global export/import trade in goods worth USD 324 billion. Geographically, COMESA covers almost two thirds of the African Continent with an area of 12 million (sq km). The region aspires to create an enabling environment and legal framework which will encourage growth of the private sector, the establishment of a secure investment environment and the adoption of common sets of standards. Eleven Member States have signed into a Free Trade Agreement (FTA) and the region is moving towards a fully functional Customs Union. Appropriate institutional structures have been set up to effectively drive the regional agenda these include the COMESA Secretariat, Business Council as well Trade and Development Bank, among others.

The socioeconomic diversity of the Member States strongly positions the region to be a key global player in international trade (both intra and extra regional). The pharmaceutical sector is among the sectors that has been prioritized by the region from both a public health and industrial development perspective. Indeed, the sector is among the nine key priority sectors that have been identified by the COMESA Industrialisation Strategy: 2017-2026[1]. Further, the COMESA Health Framework (2016), urges Member States to put in place enabling policy and legal frameworks for investments (local and foreign) in pharmaceutical production[2].

In 2020, the region imported pharmaceuticals worth USD 5.6 billion and exported USD 457 million[3]. The intra-COMESA imports were reported at USD 180 million and USD 178 million for 2019 and 2020 respectively indicating an overreliance (approx. 97 percent) of imports from outside the region[4]. Egypt and Kenya have well established pharmaceutical industry with other countries like Ethiopia and Tunisia beginning to attract significant investments in the sector owing to well thought out strategic interventions. Despite the huge and rising demand for pharmaceuticals and other medical products, local manufacturers lose out to imports. The reasons for this are varied but range from lack of capacity to produce inputs such as active pharmaceutical ingredients, high production costs and policy incoherence at the interface of health, trade and industrialization.

The overreliance on imports was laid bare during the COVID pandemic which caused supply chain disruptions. The prices of active pharmaceutical ingredients and the finished pharmaceutical products shot up significantly during the early phase of the pandemic with some products being unavailable altogether as source countries restricted imports. Other COVID related items such as personal protective equipment (PPEs) and oxygen supplies were in short supply owing to high global demand, export restrictions and lack of local capacity. Further, the region and Africa in general relied on donations and purchased imports for COVID vaccines with 17.2 percent and 12.8 percent of the targeted population having received the first and second dose respectively as at the end of March 2022[5].

There exists local capacity to manufacture and supply COVID related pharmaceutical goods and services in the region with some countries having well established manufacturing bases but face market

1 COMESA Industrialization Strategy: 2017 -2026
2 COMESA Health Framework (2016)
3 ITC calculations based on UN COMTRADE and ITC statistics
4 COMSTAT Database
5 COVID-19 vaccination in the WHO African region Bulletin, March, 2022

access constraints and unfavourable framework conditions that impact on firm level competitiveness. These include high cost of inputs including utilities, poor enforcement of existing regulations resulting in unfair competition from imports and substandard products as well inconsistent application of incentives amongst others. Leveraging on an integrating market, improving policy coherence and understanding supply-demand dynamics of the region as well as pooling supply requirements for economies of scale could address the existing challenge. A well-established regional pharmaceutical and medical products manufacturing that supplies lifesaving commodities, reduces dependence on imports, builds pandemic resilience and promotes industrialization has been prioritized by the region.

It is in this regard that the African Development Bank (AfDB) supported the COMESA Secretariat to carry out market research to identify and analyse supply and demand gaps in COVID-19 related pharmaceutical goods and services in the COMESA region. This report highlights the findings of the study with a focus on; regional supply-demand landscape for selected pharmaceutical and medical products including key actors in the market; industry mapping identifying hotspots for domestic suppliers and countries with supply gaps; and investment opportunities across product and functional use portfolio.

In addition, through a value chain approach, the existing regional and national policy frameworks are analyzed with view to identifying intra-regional trade drivers and constraints. The report highlights the strategic entry points in order to fully utilize the opportunities available in the markets for the COVID-19 products and services. Finally, the report contains recommendations for enabling the optimum production, trade and utilization of the COVID-19 pharmaceutical and medical products in the region.

1.1 Rationale, objective and scope

The major challenges facing the pharmaceutical industry in the COMESA region have been identified to include the following; the need for data collection on the capacity gaps in the countries and the supply base; the need to strengthen operational capacity of the local manufacturers who have shown potential of producing mass and at low cost; lack of proper market analysis in the region of the supply and demand position of the COVID-19 related pharmaceutical products and services and the continued importation from outside the region. In addition, there is lack of a well-developed and fully integrated regional pharmaceutical value chain to leverage on the existing opportunities.

The main objective of the study, therefore, was to identify and analyze supply and demand gaps of COVID-19 related pharmaceutical goods and services in 10 selected COMESA Member States, including, Egypt, Eswatini, Ethiopia, Kenya, Madagascar, Mauritius, Tunisia, Uganda, Zambia and Zimbabwe. These included highlighting the demand and supply gaps of COVID-19 related pharmaceutical products and services as well as disinfectants/sterilization products, protective garments of textiles, face masks and eye protection, COVID-19 vaccines among others, and determining the market potential of these products in the region.

Specifically, the scope of the assignment included the following:

i. Conducting a situational analysis of the demand and supply of the pharmaceutical goods and services in the selected countries;

ii. Conducting a market and value chain analysis of selected pharmaceutical goods and services available including;

   a. Description of key markets, including market composition maps and key players;

   b. SWOT Analysis for the pharmaceutical sector.

iii. Identifying where production of COVID-19 supplies is taking place and which are the players in producing these supplies in the selected countries;

iv. Analyzing the challenges that hinder sustainable production as well as opportunities for trade of these selected products and services in the region;

v. Analyzing the commercial viability of the products into the market including supply and value chains;

vi. Highlighting strategic entry points and undertakings for enhanced participation in the market;

vii. Identifying capacity gaps (supply and demand) of local pharmaceutical companies in sustainable production, utilization and marketing of these pharmaceutical goods and services;

viii. Providing recommendations for enabling the optimum production, trade and utilization of the COVID-19 pharmaceutical products and services in the region;

ix. Providing recommendations on the strategic entry points to fully utilize the opportunities available in the markets for the COVID-19 products and services.

2 Approach and Methodology

The assignment began with a kick off meeting with the Directorate of Industry and Agriculture, COMESA Secretariat on 18th January 2021. The purpose of meeting was to ensure a common understanding of the assignment and the listed deliverables as per the terms of reference (TOR). During the kick off meeting the consultant sought clarifications and requested relevant reports and publications from the Secretariat. A tentative timeline for the visits and stakeholder meetings was also discussed.

This was followed by an in-depth desktop literature review with a particular focus on existing regional protocols and policies, national policies and strategies, market reports as well global and continental initiatives. A data collection tool which sought to capture both qualitative and quantitative aspects of the assignment was designed. This was particularly important as physical visits were only envisaged in three out of the ten selected countries. The stakeholders interviewed included the following;

- Public sector representatives
- Manufacturers, distributors
- National and regional business support organisations

- Development Finance Institutions and International Development Partners
- Civil Society Organisations (CSOs)

The quantitative and qualitative data collected during literature review and interviews were analyzed to produce a draft report which was shared with the COMESA Secretariat and the African Development Bank for input. The report was revised based on the input from the Secretariat and the Bank. The revised draft report will be presented to stakeholders in a regional validation workshop for their input and revised accordingly to produce a final report.

3 Overview of Production and Supply of COVID-19 Supplies

This section highlights the production and supply of COVID-19 supplies from a global, continental and regional perspective. It begins with an overview of the economic impact of the COVID-19 pandemic in Africa and the region, then describes the impact on the health technologies value chains including vaccines. It ends with an overview of the continental and regional initiatives that are aimed at strengthening local production of health technologies.

3.1 The Economic impact of COVID-19

The Coronavirus emerged in China in December 2019 and spread globally during the first quarter of 2020 (WHO,2020a). The transmission control policies implemented by governments simultaneously triggered severe economic disruption affecting supply, demand and trade. Supply has been affected directly through the suspension of operation of economic units across multiple activities. This has led to redundancies and suspensions, which directly affected demand through dampening income expectations. The lockdowns directly affected many services, such as hospitality and retail services, with a knock-on effect on their domestic and foreign suppliers (ATPC,2020).

The crisis has had strong effects on Africa. When the pandemic hit in 2020, the continent's combined Gross Domestic Product (GDP) contracted by 2.1 percent (ATPC, 2020). The contraction was largely driven by African governments implementing strict lockdowns amid fears that Covid-19 would overrun fragile health services across the continent. In 2021, Sub-Saharan Africa GDP grew by a modest 3.7 percent according to the IMF, driven by a partial resumption of tourism, a rebound in commodity prices and the rollback of pandemic-induced restrictions. However, the outlook for 2022 looks barely unchanged as the Fund predicts that sub-Saharan Africa's growth will only increase by 0.1 percent to 3.8 percent (Africa Report, 2022).

Africa is primarily involved upstream, providing intermediate products and services to a wide range of global supply chains. African exports, including their value added, were therefore being affected simultaneously by the impact on direct exports but also by the impact on exports between third countries. African economies are significantly integrated into supply chains as buyers. In some cases, African companies import intermediate goods to be further processed on the continent to be transformed into final goods. In other cases, imports of final products are commercialised through African retailers and wholesalers[6].

6 Ibid

The COMESA region's average growth contracted sharply in 2020, shrinking by 5.4 percentage points to 0.2 percent, from 5.6 percent in 2019, but is projected to rebound to 6.0 percent in 2022, respectively[7]. This is attributed to the fact that growth plummeted to negative levels in a number of COMESA Member States. Growth outcome in 2020 was negatively impacted by the COVID-19 induced health and economic crisis including, among others, the following:

- impact of containment measures and the decline in global demand for goods and services;
- external financial constraint involving capital outflows and sharp declines in capital inflows and remittance.

The region prioritised containing the spread of COVID-19 as well as opening up the regional economy. In this regard, the region developed and adopted the Guidelines for Sustainable and Inclusive Industrial Production of Goods and Services across the COMESA region during and after the COVID-19 pandemic (COMESA, 2020). The guidelines amongst other interventions proposed the following;

- Facilitating and encouraging local production of essential goods and services including COVID-19 personal protective equipment (PPE) by private and public sectors within the region;
- Accelerating public-private sector investment in local production of pharmaceutical goods and services;
- Developing regional-wide procurement platforms and end-to-end supply chains.

Other interventions identified included the speedy rollout of COVID-19 vaccines and mass testing. At the national level, some Member States abolished or reduced tariffs and taxes to facilitate trade in pharmaceuticals and medical supplies in the fight against Covid-19. These included Burundi, DR Congo, Ethiopia, Malawi, Somalia, Tunisia, Uganda, Zambia and Zimbabwe (COMESA, 2020b). On the other hand, Egypt, Kenya, Eswatini, Libya, Madagascar and Zimbabwe imposed export restrictions and export licensing requirements on medical supplies, masks, ventilators, hand sanitizers among others[8]. The export restrictions led to increase in prices for the pharmaceutical products in the region slowing down the fight against COVID-19.

3.2 Impact of COVID-19 on Health Product Technologies Value Chains

COVID-19 has demonstrated the heavy import dependency and vulnerability of Africa's pharmaceutical sector. All African countries are net importers of medical and pharmaceutical products, with Africa importing 94 percent of its pharmaceuticals in total (UNECA,2020). In the case of imports into Africa, India's share is higher than China's for drug formulations across the 10 largest export markets of pharmaceuticals in Africa; South Africa, Egypt, Morocco, Kenya, Algeria, Ethiopia, Tunisia, Sudan, Tanzania and Nigeria. However, with regard to bulk drugs, China exported more to five of these 10 markets (Kurian, C. and Kapoor, K., 2020). Local manufacturers produce 25 –30 percent of pharmaceuticals and less than 10 percent of medical supplies that are on the African market. Africa has

7 COMESA Annual Report, 2020
8 Ibid

an estimated 375 pharmaceutical manufacturers all formulating finished products from APIs sourced from India and China. An estimated 100 manufacturers in Sub-Saharan Africa are limited to packaging. Only two companies in South Africa are producing APIs and none is involved in significant research and development (McKinsey & Company, 2019).

To contain the spread of the virus, several countries, including those that are key players in global pharmaceutical value chains such as China and India put in place containment measures, which included closure of factories, social distancing and travel bans, all of which severely affected pharmaceutical supply chains globally. This supply chain disruption had global repercussions as 70 percent of all active pharmaceutical ingredients used in Indian drug production come from China, and India is responsible for 20 percent of pharmaceuticals production in volume terms globally (Rude, J., 2020).

As the pandemic unfolded, African manufacturers experienced the collapse of input supply chains, with increases in imported input prices alongside escalating freight costs. Buyers' payments slowed, exacerbating the financial squeeze on manufacturers. Lack of local input suppliers, especially in APIs, medical grade fabric and plastics, and high-quality packaging, alongside weak local testing and accreditation capability, constrained local manufacturers' outputs just as demand escalated (DERP,2021).

Despite the challenges, African manufacturers responded to COVID-19 requirements through scaling up and product innovation. The companies produced essential pharmaceuticals that were widely used in COVID-19 management as well sanitisers, masks, gloves, overshoes, face shields, medical scrubs, PPEs of various quality including medical grade, ventilators and test kits[9].

Box 1. **A snapshot of global supply-demand dynamics for selected health commodities**

- The total imports and exports of medical goods were valued at USD 1,286 billion in the first half of 2021. This represents a growth of 12.4 percent compared to the same period of 2020 (WTO,2021).
- As vaccination numbers increased, the highest year-on-year growth was for medical supplies, including items critical for administering vaccines (i.e., rubber gloves, syringes and needles), which grew by 34.8 percent.
- The supply of these items, especially rubber gloves, is geographically concentrated. Four of the top five suppliers were countries in Asia and accounted for 86 per cent of the export market for gloves, with Malaysia's share at 54 percent.
- In the first quarter of 2020, the trade of rubber gloves, syringes and needles accounted for only 10 percent of trade in medical supplies, but that share almost doubled to more than 18 percent by the second quarter of 2021.
- Exports of syringes and needles are less concentrated. Although the United States and China were the top suppliers, their combined share of world exports was only around 27 percent.
- Trade of testing materials and diagnostic reagents remains high, which grew by 54.5 percent in the first half of 2021 compared to the same period of 2020.

Source: WTO (2021), Trade in medical goods in the context of tackling covid-19: Developments in the first half of 2021

9 Ibid

Protective devices, which were in high demand, included masks, gloves, sanitising products and hospital gear, such as aprons and bodysuits. China accounts for 41 percent of all PPE imports to Africa, followed by France (8 percent), Spain (6 percent) and (5 percent) Germany (OECD, 2020). However, about 11 percent of PPE exports from African countries are for intra-African trade and this percentage goes up to 19 percent for protective garments, indicating local capabilities in this segment that could be scaled-up[10]. South Africa is the top exporter within the continent, accounting for 7 percent of exports of all PPE items.

During the early stages of the COVID-19 pandemic, there was widespread global shortages and price hikes for PPEs. Africa was the most impacted owing to the limited production capacity that existed. However, in response to the pandemic, African governments including those in the COMESA region quickly mobilised actors in both public and private sector to scale production. Textile companies were retrofitted, or production lines were repurposed to manufacture PPEs. Local production capacities have been built across the region however the challenge of complying and enforcing product standards persist.

Global exports of ventilators averaged at USD 6.8 billion annually during 2016-18 and five countries account for over half of total world exports. The top exporters are the United States (13 percent), Germany (11 percent), Singapore (11 percent), Australia (11 percent) and China (10 percent). China is the leading trading partner for Africa, accounting for 20 percent of continental imports, followed by the United States (17 percent) and Germany (12 percent). Intra-African trade in respiration machines is 2.5 percent of Africa's import, with South Africa being the main continental provider. The pandemic has created a huge unmet demand for ventilators with reports indicating that the global demand is ten times the current supply capacity. The demand for Africa is estimated between 30,000 to 40,000 (Bloomberg, 2020). In addition, the prices range from USD 20,000 to USD 50,000 per unit depending on sophistication and technology[11].

During the pandemic, countries restricted exports of the ventilators and ramped up production through various incentives and advanced market commitments. Various universities and companies across the continent ventured into ventilator production starting with prototypes. While there has been reported successes in producing prototypes, companies and research groups struggle to scale up. The key challenges have been meeting the required safety standards, accessing regulatory approval and affordability.

Generalised testing became the shared goal for all countries to safely ease restrictions, restore trust and gradually reopen economies. A third of all tests (35 percent) have been commercialised by Chinese companies, followed by the United States (13 percent) and (12 percent) Korea (FIND,2020). Companies in the United States account for 26 percent of in-development tests, of which the majority are serological tests that have the potential to deliver mass testing. In Africa, two private firms from Egypt have commercialised one test each, and companies in Ghana, Kenya, Nigeria, Senegal, South Africa and Uganda are also producing tests (ECA,2020).

10 Ibid

11 Open (2020), https://www.open.online/2020/03/31/coronavirus-europa-e-a-corto-dimascherine-e-ventilatori-polmonari-quali-sono-i-limiti-della-produzione

3.3 Supply and Production of COVID- 19 Vaccines

The COVID-19 has exposed Africa's lack of local production capacity and led to a sense of urgency and renewed public commitments, creating unprecedented alignment around African vaccine manufacturing. Today, 98-99 percent of Africa's routine vaccines are imported and a majority of volumes are supplied by a small group of manufacturers mainly from India (AU CDC, 2021). The African public vaccine market totals USD 1.3 billion, with forecasts suggesting it could be worth USD 2.3 to 4.3 billion by 2030 as a result of expanding access and growing populations. In 2020, the COMESA public market was estimated at USD 451 million and is expected to grow to between USD 940 million and USD 1.5 billion by 2030[12].

Significant buyer consolidation exists today with the Global Alliance for Vaccines and Immunization (GAVI) supporting approximately 90 percent of the market by volume and 66 percent by value. UNICEF procurement provides secure, long-term contracts for large volumes, but manufacturers are held to strict quality requirements and low pricing, requiring significant economies of scale to be competitive

Currently less than 1 percent of Africa's vaccines are locally manufactured, presenting an untapped opportunity for local manufacturers to enter or expand production. The few African vaccine manufacturers are consolidated in 5 countries (South Africa, Morocco, Tunisia, Egypt and Senegal) and only a few conducting upstream manufacturing activities with the majority focusing on fill and finish or labelling and packaging. Senegal (Pasteur Institut, Dakar), in Egypt (Vacsera) and Pasteur Institute of Tunisia have limited volume drug substance manufacturing, fill-finish, along with packaging and distribution. Biovac and more recently Aspen, both from South Africa, have a fill and finish capacity.

The current lack of COVID-19 vaccines has clearly exposed the continent's vulnerability. Only 12.8 percent of the African continent's population has been fully vaccinated with only two countries having surpassed 70 percent of people fully vaccinated: Mauritius (75.8 percent) and Seychelles (81.5 percent). Four countries have fully vaccinated between 40 percent and 70 percent of their population: Mozambique (42 percent), Botswana (55 percent), Cabo Verde (55 percent) and Rwanda (62 percent) as the end of March 2022[13].

The continent is making efforts to rapidly scale up vaccine access with new initiatives and partnerships being announced in Rwanda, Ghana, Senegal, Nigeria, Algeria, Egypt, Kenya, Senegal and South Africa. A majority of the new initiatives are targeting fill and finish however a few such as in Kenya, Rwanda, Senegal and South Africa are aiming for drug substance manufacture. The African Union New Partnership for Africa's Development (AU-NEPAD), Africa Centres for Disease Control (CDC) along with pan African finance institutions such as Afreximbank and African Development Bank as well as international development partners have come together towards a common objective of accelerating vaccine production and access across the continent.

Specifically, the African Union and African CDC have launched the Partnerships for African Manufacturing (PAVM) framework to focus on overall roadmap, strategy and execution support for achieving the target of 60 percent on-continent manufacturing by 2040[14]. The World Health Organisation (WHO) has launched an mRNA technology transfer hub which aims to build capacity in low- and middle-

12 Ibid
13 COVID-19 vaccination in the WHO African region Bulletin, March, 2022
14 PAVM Framework for Action, (2022)

income countries to produce mRNA vaccines through a centre of excellence and training. The hub is located at Afrigen, Cape Town, South Africa, and will work with a network of technology recipients (spokes) in low- and middle-income countries[15]. Three of the six African countries identified as the first recipients of the technology transfer are COMESA Member States namely, Egypt, Kenya and Tunisia. The other three African countries include Senegal, Nigeria and South Africa.

3.4 Continental and regional initiatives to promote local production

Before the COVID-19 pandemic, there were already existing continental, regional and national initiatives across Africa to reverse the trends on over reliance on imports and to improve access to quality medicines and other health commodities. The emergence of COVID-19 has added a sense of urgency. These initiatives and others established in response to the pandemic are highlighted below;

Continental level

The African Union has developed the Pharmaceutical Manufacturing Plan for Africa (PMPA) Business Plan which provides a high-level roadmap towards strengthening local production of medicines for public health and industrial development (AUC,2012). The PMPA is designed to catalyse local pharmaceutical production which in turn should contribute to improved public health outcomes on the one hand and economic benefits on the other. The plan proposes a package of solutions to the critical challenges facing the pharmaceutical industry to be delivered through multisectoral and multistakeholder actions.

The African Medicines Regulatory Harmonization (AMRH) is an initiative of the African Union (AU) that aims to strengthen regulatory capacity, encourage harmonization of regulatory requirements and expedite access to good quality, safe, and effective medicines The initiative is implemented as part of the AU's PMPA, a policy framework to provide an enabling regulatory environment for local production and contribute to the UHC, AU Agenda 2063 and SDGs goals. It is being implemented in the Economic Community of West African States (ECOWAS), Intergovernmental Authority on Development (IGAD), Economic Community of Central African States (ECCAS), East African Community (EAC) and the Southern Africa Development Community (SADC). It covers more than 85 percent of the Sub-Saharan African countries and are at different levels of implementation.

In order to address the problem of non-coherent medicines laws in African countries, the AMRH Initiative developed a Model Law on medical products regulation so as to ensure effective regulation and promotion of harmonization. The Model Law which among others promotes the establishment of autonomous agencies was adopted by the AU Assembly in January 2016 and has been domesticated by more than 12 AU Member States (Ndomondo-Sigonda ,2021). In addition, the Bureau of the African Union Heads of State and Government endorsed in 2019 the Treaty for the establishment of the African Medicines Agency (AMA) to enhance the capacity of countries to regulate medical products. AMA would support ongoing medicines regulatory harmonisation efforts at the regional economic communities. The Treaty for the Establishment of the African Medicines Agency (AMA) entered into force on 5th November 2021 after the deposit of the 15th instrument of ratification. In addition, the African Medical Devices Forum (AMDF) advises National Regulatory Authorities on the development of relevant guidelines and testing for medical devices including PPEs. The forum has prioritised their support towards strengthening the regulation of invitro diagnostics.

15 https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

The African Union Joint Continental Strategy for COVID-19 Outbreak includes specific provisions to address gaps in testing capacities, from pooled procurement and warehousing to standardisation, and mechanisms to channel financing where it is needed the most[16]. On access to appropriate financing, the Africa Export Import Bank (AFREXIMBANK) has introduced a USD 3 billion facility which among other interventions will provide funding for the scaling up of manufacturing of COVID-19 requirements that can be produced in Africa and sent across borders. The African Development Bank (AfDB) on the other hand, has raised USD 3 billion in a three-year bond to help alleviate the economic and social impact of the pandemic on Africa. In addition, the AfDB launched a USD 10 billion COVID-19 Response Facility to assist regional member countries in fighting the pandemic.

Regional (COMESA) level

The COMESA Industrialisation Strategy and Action Plan: 2017-2026, includes pharmaceuticals as among the priority areas for the region. Amongst other objectives, the strategy aims to increase intra-regional manufactured exports relative to total manufactured imports to the region from the current 7 percent to 25 percent by 2026. The selected value chains would be upgraded through enhanced productive capacities; promoting entrepreneurship, production linkages and industrial clusters. The strategy has also prioritised the promotion of intraregional trade in manufactured goods.

The COMESA Health Framework (2016) highlights the strategic importance of strengthening local production of essential medicines and the need to leverage on public health related World Trade Organisation Trade Related aspects of Intellectual Property Rights (WTO TRIPS) flexibilities. Further, the COMESA Guidelines (May,2020) for sustainable and inclusive industrial production during and after COVID-19 Pandemic puts more emphasis on regional production of pharmaceutical goods and services (COMESA, 2021). The region has also established the COMESA COVID-19 Online Platform for exchanging and sharing information on availability of essential products within Member States. In collaboration with the EAC and SADC, the region has developed the Tripartite Guidelines on Trade and Transport Facilitation for Safe, Efficient and Cost-Effective Movement of Goods and Services and the Tripartite Guidelines for Safe Cross Border Movement of Persons and Personal Goods[17]. Some of these measures though implemented to address the COVID-19 pandemic will have a lasting and sustainable positive impact on promoting local production of pharmaceuticals and other medical supplies.

At the national level, good examples exist such as the establishment of pharmaceutical parks with shared services infrastructure in Ethiopia as well incentives such as advance payments for orders and tax-free loans and tax holidays for new investments. Another notable development is the recently established Gypto Pharma City in Egypt which aims to attract global players in pharmaceuticals and biologicals. Across the region, there is preferential treatment accorded to local manufacturers to level the playing field with imports. The report, therefore takes cognisance of the above initiatives and the proposed recommendations will seek to leverage on the same.

3.4.1 African Continental Free Trade Area

The agreement establishing the African Continental Free Trade Area (AfCFTA) came in to force on 30 May 2019 with 24 countries having ratified the agreement. The operational phase of the AfCFTA was launched in July 2019 and as of May 2020, 43 of the 54 signatories had deposited their instruments of

16 https://africacdc.org/download/africa-joint-continental-strategy-for-covid-19-outbreak/
17 https://wwaw.tradeeconomics.com/wp-content/uploads/2021/12/COMESA-Webinar-Presentation.pdf

ratification[18]. The AfCFTA is a flagship initiative of the African Union's Agenda 2063. The agreement will create the largest free trade area in the world measured by the number of countries participating. The pact connects 1.3 billion people across 55 countries with a combined gross domestic product (GDP) valued at USD3.4 trillion. The AfCFTA would significantly boost African trade, particularly intraregional trade in manufacturing. The AfCFTA is being implemented in two phases. Phase I provides a framework for the liberalisation of trade in goods and services, and a mechanism for dispute settlement. For trade in goods, the agreement sets the path for eliminating tariffs on 90 percent of product categories (World Bank, 2020)

The positive impact of the AfCFTA is expected to be significant. By 2035, the volume of total exports is projected to increase by almost 29 percent with intra-continental exports increasing by more than 81 percent, while exports to non-African countries would rise by 19 percent (World Bank,2020). Under the AfCFTA scenario, manufacturing exports would gain the most, 62 percent overall, with intra-Africa trade increasing by 110 percent and exports to the rest of the world rising by 46 percent[19]. This would create new opportunities for African manufacturers and workers. These gains would come, in part, from decreased tariffs and even greater gains would come through implementation of trade facilitation measures.

The agreement will reduce tariffs among member countries and cover policy areas such as trade facilitation and services, as well as regulatory measures such as sanitary standards and technical barriers to trade. It will complement existing subregional economic communities and trade agreements in Africa by offering a continent-wide regulatory framework and by regulating policy areas such as investment and intellectual property rights protection that so far have not been covered in most subregional agreements in Africa.

Furthermore, the pandemic has demonstrated the need for increased cooperation among trading partners. By replacing the patchwork of regional agreements, streamlining border procedures, and prioritizing trade reforms, AfCFTA could help countries increase their resiliency in the face of future economic shocks. The health sector needs to be elevated as the heart of the AfCFTA Agreement and prioritised in the initial stages of implementation. Pharmaceutical and medical products should not be included on the sensitive item or exclusion lists of state parties' tariff schedules and should be prioritised in the finalisation of rules of origin and harmonisation of standards.

Indeed, the United Nations Economic Commission for Africa (UNECA) has launched the AfCFTA-Anchored Pharmaceutical Initiative as part of its mandate to deliver on Agenda 2063, the SDGs and operationalization of the African Continental Free Area (AfCFTA). The project was commissioned in 10 pilot countries with a key objective to address socio-economic-related challenges facing African Member States in improving access to maternal, neonatal and child health (MNCH) essential medicines and commodities. The Initiative pursues a three-pillar approach to build up the continent's healthcare industry through managed pooled procurement of pharmaceutical (PPP) products in the pilot countries, facilitate local production of pharmaceuticals and lastly, to ensure a sustainable harmonized regulatory, quality, and standards of medicines and related medical products[20].

18 https://www.tralac.org/resources/infographic/13795-status-of-afcfta-ratification.html
19 Ibid
20 https://www.uneca.org/afcfta-anchored-pharma-initiative

4 Findings of the Study

This section highlights the findings of the study based on review of market data, reports and interviews with stakeholders. It begins with an overview of the regional supply-demand dynamics on the various product categories followed by a description of industry and market structure with a focus on the study countries. The section ends with a value chain analysis of selected product groups.

4.1 Regional Supply-Demand Dynamics

4.1.1 Pharmaceuticals

The COMESA region imported a total of USD 5.63 billion in 2020 compared to USD 6.16 billion worth of pharmaceuticals in 2019, a decrease of 9 percent[21]. The main source countries in 2020 for the region were India and Switzerland with imports of USD 1.145 billion and USD 1.104 billion from the two countries respectively, making a combined share of 39 percent[22]. The intra-COMESA imports was reported at USD 180 million and USD 178 million for 2019 and 2020 respectively indicating an overreliance (approx. 97 percent) of imports from outside the region[23]. Over the same period, COMESA exported USD 443 million and USD 457 million in 2019 and 2020 respectively, reflecting a modest increase of USD 3.2 percent.

Egypt and Kenya were both the leading importers and exporters of pharmaceuticals as shown in Table 1 and 2 as well as Figure 1 and 2 below. For example, in 2020, the share of imports and exports by Egypt were 40 percent and 59 percent respectively. In the same period, the top 5 exporters had a combined share of 99 percent of the total exports while the top 5 importers had a combined share of 75 percent.

Table 1. Top 5 importers of pharmaceuticals

Importers	Imports USD, 000	
	2019	2020
COMESA Total	6,169,427	5,635,638
Egypt	2,605,674	2,264,286
Kenya	557,246	690,138
Ethiopia	638,411	580,495
Libya	391,093	393,901
Uganda	300,886	351,485

21 ITC calculations based on UN COMTRADE and ITC statistics
22 Ibid
23 COMSTAT Database

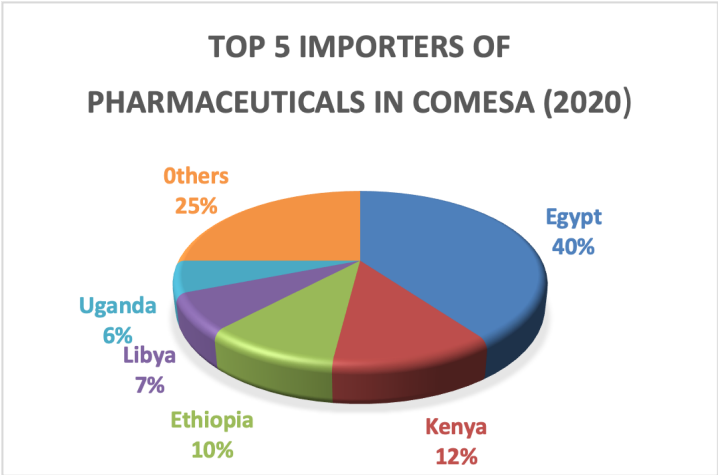
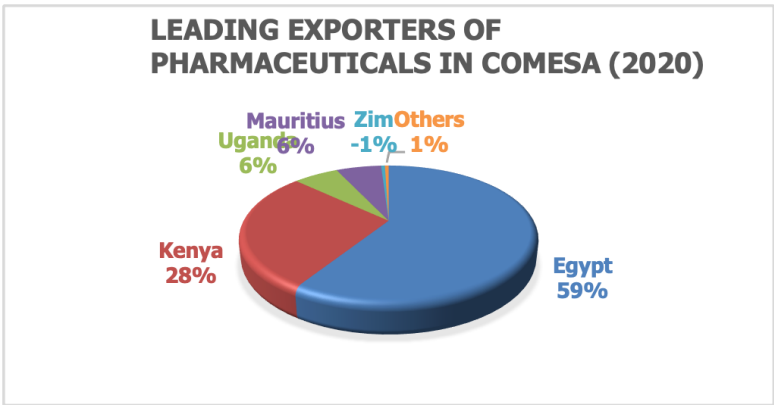


Figure 1. Top 5 importers of Pharmaceuticals in 2020

Table 2 . Top 5 Exporters of pharmaceuticals

	Exports USD, 000	
Exporters	**2019**	**2020**
COMESA total	443,900	457,013
Egypt	271,848	267,918
Kenya	116,528	128,519
Uganda	13,492	28,208
Mauritius	32359	25,262
Zimbabwe	2,,965	2,190

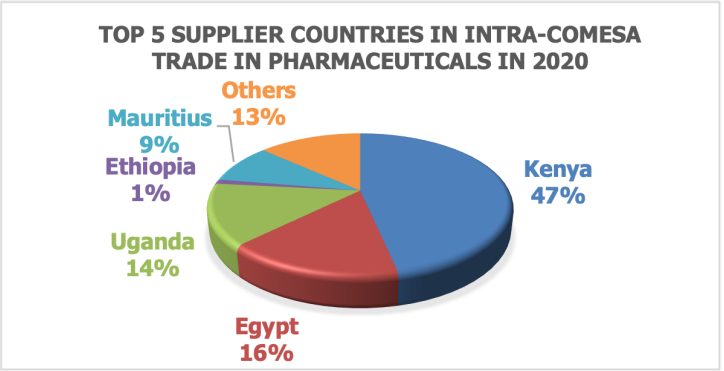
Figure 2 . Top 5 exporters of pharmaceuticals in 2020



Source: ITC calculations based on UN COMTRADE and ITC statistics, COMSTAT Database

On intra-regional trade, Kenya and Egypt dominate in exporting to the other countries in the region. As seen on figure 3 below, Kenya leads with share of 47 percent of the total value of intraregional trade in pharmaceuticals in 2020, followed by Egypt with 16 percent and Uganda at 14 percent. The top 5 supplier countries in 2020 have a combined share of 87 percent demonstrating a dominance of intraregional trade by a few countries. Further as seen on table 3, Kenya exports to a total of 14 COMESA countries with Egypt exporting to 11 countries. A closer examination of export destinations from the supplier countries indicate that geographic proximity plays a key role as seen on table 3 below. For example, Zimbabwe export destinations is to the neighbouring countries of Zambia, Malawi and Eswatini, and a similar trend is notable in most of the countries. Even for the leading pharmaceutical producers in the region the same applies as shown by their export volumes, for Kenya, exports to Uganda account for 38 percent of her total exports to COMESA while for Egypt exports to Libya account for 44 percent as seen in Figure 4 below.

Figure 3. Top 5 supplier countries in Intra-COMESA Trade in Pharmaceuticals (2020)

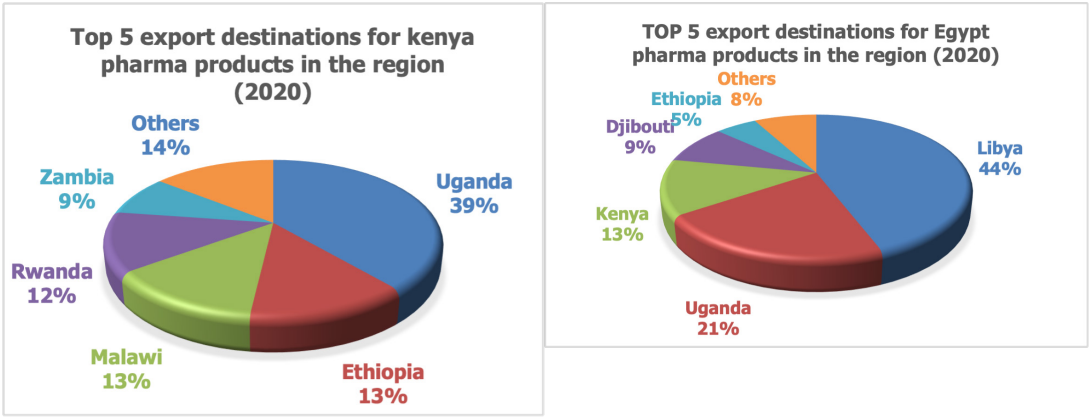


Source: ITC calculations based on UN COMTRADE and ITC statistics, COMSTAT Database

Table 3. Snapshot of export destination in COMESA by the selected study countries

Exporting Country	Importing Country
1. Egypt	Libya, Uganda, Kenya, Djibouti, Ethiopia, Burundi, Eritrea, Zambia, DRC, Rwanda, Mauritius (11 countries)
2. Kenya	Uganda, Ethiopia, Malawi, Rwanda, Zambia, DRC, Burundi, Mauritius, Djibouti, Zimbabwe, Eswatini, Madagascar, Seychelles, Libya (14 countries)
3. Ethiopia	Uganda, Kenya, Djibouti, DRC, Zambia, Comoros, Burundi
4. Uganda	Kenya, Zambia, Burundi, Malawi, Zimbabwe, DRC, Rwanda
5. Mauritius	Madagascar, Seychelles, Comoros, Zimbabwe, Rwanda
6. Tunisia	Libya, Djibouti, Burundi, Madagascar
7. Zambia	Malawi, Zimbabwe, Uganda, DRC
8. Zimbabwe	Zambia, Malawi, Eswatini
9. Eswatini	Zimbabwe, Eritea
10. Madagascar	Comoros, Djibouti, Malawi

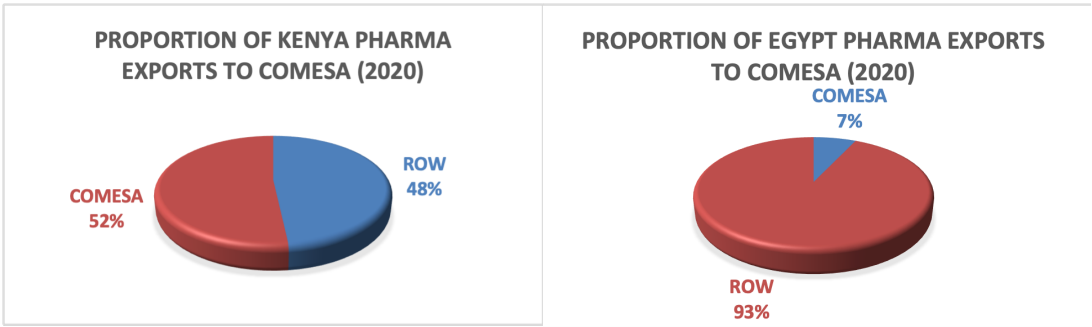
Figure 4 . Top 5 export destinations for Kenya and Egypt pharmaceutical products in the region (2020)



In 2020, Kenya exported USD 66.4 Million out of a total of USD 128.5 million (total pharmaceutical exports) to COMESA region compared to USD 61.9 million in 2019 reflecting an increase of 7.2 percent. The proportion of Kenyan pharmaceutical exports to COMESA market was 52 percent of her total pharmaceutical exports indicating the significance of the regional market to the country (see figure 5). In 2020, Egypt exported USD 18.7 Million out of a total pharmaceutical export of USD 267.9 Million to

COMESA compared to USD 19.3 million in 2019, indicating a decline of 3.2 percent. The proportion of Egypt's pharmaceutical exports to COMESA stands at 7 percent of her total pharmaceutical exports (see figure 5).

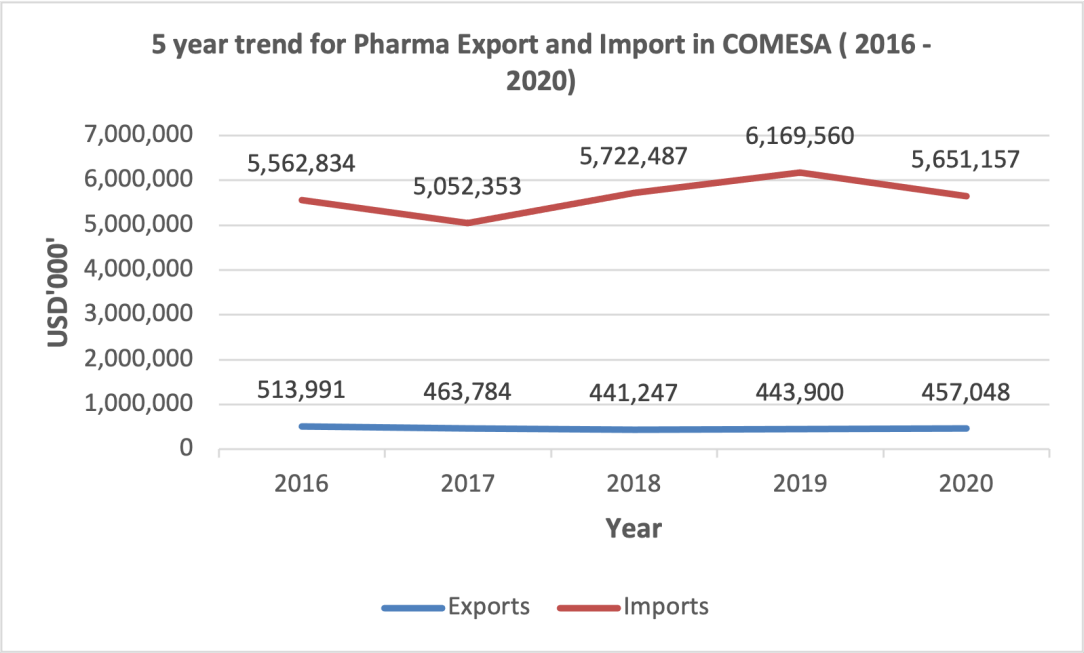
Figure 5 . Proportion of Egypt and Kenya Pharma exports to COMESA (2020)



Source: ITC calculations based on UN COMTRADE and ITC statistics, COMSTAT Database

The total imports of pharmaceuticals to COMESA were USD 5.65 billion in 2020 while the total exports were only USD 457 million in the same period. The trends for imports as shown in the figure below indicates modest increase between 2016 and 2020, with an 8 percent drop in imports in 2020 compared to 2019. The drop could be attributed to COVID-19 supply chain disruptions from source countries. The data as seen on figure 6 indicates a huge trade imbalance favouring imports with the gap consistently remaining the same over the five-year period of 2016 to 2020. This demonstrates the need for the region to put in place deliberate measures to promote import substitution through strengthening local production.

Figure 6. A 5-year trend for pharma export and import in COMESA (2016-2020)



Source: ITC calculations based on UN COMTRADE and ITC statistics

4 .1.2 COVID-19 related supplies

In reviewing the COVID-19 related supplies, the World Customs Union classification reference of COVID -19 supplies was used[24]. The imports, exports and intra-regional trade were analysed using the ITC UN COMTRADE and COMSTAT databases and table 4 below indicates trade values (2020) for selected products. It is important to note that these products are not used solely for the prevention, control and management of COVID-19 infection but also for other diseases. Therefore, the trade values indicated should not be wholly attributed to the management and control of COVID-19 infection.

24 WCO classification reference – Covid-19 medical supplies Ed. 3.01: as updated 15 January 2022

Table 4. Import, export and intra-regional trade in COVID-19 related products (2020)

Product Category	HS Code	Trade values for COVID-19 related products		
		Intra USD '000'	Exports USD '000'	Imports USD '000'
1. Ethyl alcohol (>= 80 percent)	220,710	27,901	61,973	55,392
2. Disinfectants	380,894	5,277	6,917	68,262
3. Garments	621,010	1,148	11,542	46,736
4. Wadding, gauze, bandages etc	300,590	668	2,331	43,283
5. Surgical gloves	401,511	536	2,989	49,488
6. Oxygen	280,440	907	930	2,232
7. Diagnostic or laboratory reagents	382,200	8,795	4,022	622,221
8. Syringes (with or without needles)	901,831	1,651	5,722	42,293
9. Needles, catheters, cannula etc	901,839	866	21,335	83,321
10. Ultrasonic scanning apparatus	901,812	37	169	38,368
11. Electro-cardiographs	901,811	-	22	8,052
12. Computer tomography apparatus	902,212	-	705	31,002
13. Medicaments	300,490	86,805	362,127	3,740,575

Further an analysis on exports and imports of the COVID-19 supplies for the ten study countries was done and is summarised on the table 5 below.

Table 5. COVID-19 related Exports & Imports by the study countries

Country	Exports USD '000'		Imports USD '000'	percent of total exports destined for COMESA
	COMESA	TOTAL		
Kenya	86,711	161,287	809,420	54 percent
Egypt	29,711	449,007	2,547,158	7 percent
Uganda	26,082	53,608	809,420	49 percent
Ethiopia	1,879	10,550	733,365	18 percent
Mauritius	16,750	79,930	244,334	21 percent
Zambia	16,848	21,000	427,922	80 percent
Zimbabwe	405	2,460	275,581	16 percent
Eswatini	5,431	33,150	92,185	16 percent
Madagascar	2,075	14,959	175,622	14 percent

Source: ITC calculations based on UN COMTRADE and ITC statistics, COMSTAT Database

The following are the key highlights based on analysis of trade data shown on table 4 and 5 above;

- For all the product categories the imports are several times higher than the intra-regional trade and exports respectively. The only exception being ethyl alcohol which is a key ingredient for sanitizer formulation, the exports are higher than imports demonstrating regional capacity to meet demand.
- Despite existing capacity for the region to produce disinfectants, garments and gauze bandages including availability of raw materials as well technical know-how it is still overly dependent on imports. For example, the intraregional trade in garments and exports for garments is 2.5 percent and 25 percent of import values respectively.
- A general observable trend is that the total exports were more than the intra-regional trade for all categories of products except laboratory reagents. This indicates that the region is trading more with markets outside COMESA than within herself.
- The region imported USD 622 million worth of laboratory reagents with intra-regional trade and exports being only USD 8million and USD 4 million respectively. This indicates a huge unmet demand through local production and therefore an opportunity to scale up the same.
- Significant opportunities exist for import substitution for syringes, needles and cannulas and to expand intra-regional trade as the intra-regional trade and exports from the region are only 3 percent and 13 percent of imports respectively.
- For diagnostic equipment and related consumables for ultrasound and CT scans the region is completely dependent on imports as there was no intra-regional trade reported for CT and ECG related items. The reason for this is lack of access to technology and

know-how in the region for production of the same.

- Egypt, Kenya and Mauritius are the leading exporters of diagnostic reagents, needles and syringes, with the three countries having a combined share of over 80 percent of the total exports from the region. Notably, the exports to outside of COMESA for these countries is higher than the intra-regional trade. However, the absolute values are very low when compared with imports with intraregional trade being 1.4 percent and 3.9 percent for diagnostics and needles and syringes respectively.

4.2 Industry and market structure

The industry in the region can be classified in to three broad categories based on ownership arrangements;

- 100 percent owned by local entities
- 100 percent owned by foreign entities
- Joint ownership between local and foreign entities

The companies span across the entire value chain from manufacturing to distribution and retail. The foreign owned and joint ventures are better positioned to access financing and technology, they therefore generally operate on a bigger scale with a greater product diversification and sophistication than locally owned companies. For the pharmaceutical industry, the foreign investments could be further categorised into multinationals (MTNs) mainly from the USA and Europe and those from China and India. The MTNs have innovator products in their portfolios while those from China and India are mainly generic producers.

The distribution system is mainly characterised by public and private sector actors with the former being agencies established by the respective Member States. The national medicines procurement authorities (NMPAs) purchases medical products on behalf of the state and distributes to public health facilities. The NMPAs are significant market players with potential to influence quality and price and are used by the international procurement agencies to supply beneficiary Member States. The private sector distribution is fragmented with many players and the market is yet to witness significant consolidation. The fragmentation poses a threat to supply chain integrity with potential for infiltration with counterfeit and substandard products.

In some Member States such as Kenya, Uganda and Zambia among others the faith-based procurement agencies plays a significant role in distributing medicines to health facilities. The Mission for Essential Drugs (MEDs) in Kenya for example supplies not only to faith-based hospitals but also to government and private sector outlets. The organisation has also invested in quality infrastructure with their quality control laboratories being WHO pre-qualified[25]. The laboratory has provided services including trainings to 22 African countries including COMESA Member States. During the COVID-19 pandemic the laboratory jointly worked with the national regulator on post market surveillance of hand sanitizers.

The market structure of the study countries is briefly described below including market size, key players as well any significant policy action or investments. The description is biased towards pharmaceuticals

25 https://meds.or.ke/

as the information relating to the other health commodities is not readily available owing to the nascency of the sector.

Egypt a regional hub for pharmaceuticals and medical products

At USD 4.6 billion market value (2022), Egypt is the largest producer and consumer of pharmaceuticals in COMESA. The sector is characterised by both private sector and state led investments. The private sector can be further categorised into fully owned local companies and subsidiaries to multinational companies.

In 2021, the Ministry of Health fully transferred regulatory powers over Egypt's pharmaceutical market to a new regulatory body, the Egyptian Drug Authority (EDA), in accordance with a 2019 legislation (Law 151/2019). The EDA manages new product registrations, maintain production standards, enhance pharmaceutical exports and set customs rates in imported products in order to achieve medicine sustainability. In March 2022, EDA attained WHO Maturity Level 3 for vaccines regulation (locally produced and imported), joining three other countries in Africa; Ghana, Nigeria and Tanzania with such status[26]. The Egyptian Authority for Unified Drug Procurement (EAUDP) is exclusively responsible for buying all medicinal products for governmental entities. Additionally, private entities are able to purchase their medicinal products via the EAUDP.

According to the Export Council of Medical Industries (ECMI) the country has 194 pharmaceutical manufacturing plants with nine and 10 owned by multinationals and government respectively. In addition, there are 300 and 120 plants producing medical supplies and cosmetics, respectively. For the medical supplies, 67 percent are involved in garments and other consumables, manufacturers of equipment/ instruments and medical furniture comprise 30 percent and 3 percent respectively. Some of the equipment manufacturers have attained CE mark of quality and export to African, European and Arab markets. The industry is increasingly targeting exports to other African countries, with the aim of reaching 10.0 percent market share on the continent.

Egypt's domestic pharmaceutical manufacturing industry is strong, with the main players being Egyptian International Pharmaceutical Industries, South Egyptian Drug Industries, Medical Union Pharmaceuticals, VACSERA and Amoun Pharmaceuticals. Smaller players include Jedco International Pharmaceuticals Co, Atco Pharma and Bio CarePharma while the Holding Company for Pharmaceuticals (HOLDIPHARMA) is state-owned. Multinational drugmakers hold the greatest market share in value terms, with notable players including GlaxoSmithKline, Novartis, Sanofi, Pfizer and Merck & Co. Though the multinational companies supply about two thirds of the market through direct local manufacturing or through licensing agreements, few have domestic production facilities, instead preferring to import drugs or contract manufacturing arrangement with local manufacturers[27].

The current market leaders with production facilities include Bristol-Myers Squibb, GlaxoSmithKline, Novartis and Pfizer. Other leading multinationals present in the market include France-based Servier and US-based Johnson & Johnson, Eli Lilly and Merck & Co. In 2019, Johnson & Johnson invested USD 7.8 Million in pharmaceutical operations in the country, while GlaxoSmithKline disclosed that its total investment in Egypt was USD 800 Million. Contract manufacturing has helped local firms to develop

26 https://www.who.int/news/item/30-03-2022-egypt-and-nigeria-medicines-regulators-achieve-high-maturity-level-in-who-classification-and-who-launches-list-of-regulatory-authorities-that-meet-international-standards

27 Fitch Solutions, Egypt Pharmaceuticals and Healthcare Report, 2022

good manufacturing practice standards which has, in turn, led to improvement in the competitiveness of exports[28].

Recent developments in the sector include the European Bank for Reconstruction and Development (EBRD) investing USD 750 Million in the creation of a biopharmaceutical platform designed to broaden access to vital specialty generic drugs in Egypt. In April 2021, Egypt opened, Gypto Pharma City, the largest pharmaceutical manufacturing centre in the Middle East and North Africa region with a goal to produce 150 million packs of medication per year covering 150 different drugs[29]. The facility has 20 production lines for oral solid dosage forms and 5 production lines for ophthalmology.

However, the existing pricing policy and market approval is likely to negatively affect investments. For example, Egypt's current method of pharmaceutical pricing does not allow for price increase to compensate for inflation and the pricing policy has failed to adjust for the rising costs of importing raw materials. A higher distributor and pharmacy margins are imposed on imported products compared with locally produced products thereby discriminating against multinational manufacturers. Further, the law stipulates that the authorisation of a medical product can only be issued if there is availability in the relevant box of pharmaceuticals with similar specifications, the maximum number of which is 12 products including the originator product. These existing regulations may stifle the growth of the sector.

Kenya a leading player in intra-regional trade in pharmaceuticals and medical supplies

The Pharmaceutical and Healthcare industry in Kenya is one of the fastest growing sectors in the country's economy (estimated growth rate of over 11.5 percent). In 2020, the pharmaceutical market was valued at USD 1.25 billion[30]. Local manufacturers produce over 90 percent of the products listed under Kenya's Essential Drug List, although the current overall capacity utilization is estimated by the enterprises at 40 percent. There are 40 Pharmaceutical Manufacturers directly employing 4,500 people and 20,000 people indirectly. An industry survey indicated that local manufacturers in the country generated a revenue of USD 258 million and is projected to rise to USD 687 million in 2027 (FEAPM, 2020). Most Pharmaceutical firms are located around Nairobi and constitute an important pharmaceutical manufacturing cluster in the region. Nationally, about four companies are close to reaching the highest quality standards as defined by the WHO with Universal Corporation, majority owned by Strides Shasun, India, being WHO prequalified for production of selected antiretrovirals.

Kenya's pharmaceutical companies supply about 20-30 percent of the domestic market, and export the rest to the region mainly EAC and COMESA countries. The Kenyan exports to COMESA in 2020 constituted 47 percent of total intraregional in pharmaceuticals (see figure 4 above). Over half of Kenyan firms are producing anti-infectives and are not tapping sufficiently into more lucrative immunological and cardiovascular markets that have a larger share in the region, but which need greater investments to manufacture. The largest 10 firms account for nearly 80 percent of local production, and they mainly produce unbranded generics. Most local firms compete in the same market segments with similar product portfolios. Some of the leading local manufacturers who are members of the Federation of Kenya Pharmaceutical Manufacturers include; Dawa Limited, Cosmos, Regal, Laboratory and Allied, Beta Healthcare, Medivet, Biodeal Laboratories, Universal Corporation, Nerix Pharma Ltd and Norbrook Kenya

28 Ibid
29 Interview with Export Council of Medical Industries Secretariat
30 Fitch Solutions, Kenya Pharmaceuticals and Healthcare Report, 2021

International pharmaceutical companies are showing increased interest in setting up their manufacturing plants or expanding their footprint in Kenya. For example, Square Pharmaceuticals from Bangladesh is setting up a USD 75 million manufacturing plant in one of Kenya's export processing zones (EPZs) to grow its regional reach and meet growing domestic demand in Kenya. The other entrant is Kolon Pharmaceuticals, one of South Korea's industrial conglomerates. GlaxoSmithKline East Africa, is the only innovator multinational company with a production facility in Kenya. Botanical Extracts EPZ produces crude extracts of artemether which is then exported to Europe for further processing for use as API for antimalarials and inclusion in tonic beverages.

The Pharmacy and Poisons Board (PPB), established under Chapter 244 of the Pharmacy and Poisons Act (2002), is responsible for the registration of pharmaceuticals and medical devices in Kenya. The semi-autonomous Kenya Medical Supplies Agency (KEMSA) is responsible for supplying essential drugs to public facilities, but it competes with the Mission for Essential Drugs and Supplies (MEDS) and private wholesalers.

A survey undertaken by the Ministry of Health on local production of essential health products established that 70 medical supplies (non-pharmaceuticals) are manufactured locally (MOH, 2021). These product categories include medical consumables, hospital linen and gowns with the majority of the non-pharmaceutical supplies being imported. There is only one company manufacturing syringes in the country and blood giving sets are partly manufactured and assembled locally. Two local manufacturers, Revital Healthcare and KEMRI produce laboratory diagnostics which include EDTA-K blood collection tubes 4ml, Red top / plain / silica blood collection tubes 4ml, Viral Transport Media (VTM) and ready to use bacterial culture media (both plate and tube). An increase on local manufacturing was observed during the COVID-19 Pandemic where a number of small and large-scale producers started producing personal protective equipment (PPE) with imported raw materials.

Ethiopia investing in a specialised pharmaceutical park

The Ethiopia's pharmaceutical market was valued at USD 855 million in 2019, with population of 105 million. The Ethiopian Food, Medicine and Health Care Administration and Control Authority (EFMHACA) is the country's main regulatory body for the pharmaceutical sector. In August 2018, the body restructured to become the Food and Drug Administration Authority[31].

Ethiopia has constructed the Kilinto Industrial Park, which is specialised in pharmaceutical manufacturing, with all necessary infrastructure, located in South East Addis Ababa in close proximity to the Airport and the Ethiopia Djibouti Railway line. The park was constructed with support from the World Bank at the cost of USD 204 million by the Chinese construction giant Tiesiju Civil Engineering Group Co. Ltd (CTGEGCL). It occupies 279 hectares and provides serviced land with common infrastructures such as a wastewater treatment plant, regular water supply and a dedicated power substation.

Recent investments in the country include those of Cadila which is joint venture with a local partner, others include Julphar, GlaxoSmithKline, Sandoz and Hikma, confirming an increasingly attractive environment for foreign investors in the sector. Hetero from India began construction of a cephalosporin production plant in October 2021. This is supported by the creation of an investment-friendly business environment and government incentives. Foreign investment in the industry is matched by a loan from the Ethiopian Development Bank for up to 70 percent of the investment value. Additionally,

31 Fitch Solutions, Ethiopia Pharmaceuticals and Healthcare Report, 2020

manufacturers are exempt from tax payments on 80 percent of imported materials, and loans of up to 60 percent are granted for upgrading projects during the first five years.

Ethiopia's pharmaceutical market currently consists of 22 local companies with nine involved in the manufacture of pharmaceutical products. Local companies are estimated to supply around 20 percent of the market by volume, collectively producing 90 of the 380 products in the essential medicines list. The country has 200 registered pharmaceutical importers and distributors. Medicines are supplied and distributed by a variety of private and public players as well as non-government organisations and international aid agencies.

The pharmaceutical manufacturers interviewed mentioned access to forex and raw materials as some of the key challenges for the industry. Others mentioned include, lack of regional harmonisation, lack of appropriately skilled human resource, access to finance and poor industry – academia linkages. There is lack of local capacity to produce secondary packaging materials such as aluminium foils.

The table below highlights selected incentives and other support measures offered to the industry in Ethiopia

Box 2. Highlights of incentives and other support measures

- Corporate income tax exemptions
  - ✓ APIs: up to 14 years
  - ✓ Formulations/final medicines: up to 12 years
  - ✓ Pharmaceutical packaging: up to 8 years
- Personal income tax exemptions for up 5-10 years for expatriate employees and long-term visas
- Duty and other tax exemptions on inputs and zero tax on exports
- Public procurement
  - ✓ 25 percent price preference and 30 percent prepayment for firms manufacturing in Ethiopia
  - ✓ Potential for long-term procurement guarantees
- Export facilitation
  - ✓ More accessible and competitive logistics
  - ✓ Information consolidation and market linkages

Pharmaceutical manufacturing in Uganda

The market size in Uganda is estimated at USD 700 million with 10 local drug manufacturers producing generic medicines in various dosage forms[32]. Pharmaceutical regulation in Uganda is governed by the Pharmacy and Drugs Act of 1970, as well as by the 1993 Act of Parliament that set up the National Drug Authority (NDA). The CiplaQCIL was established in 2005 as a joint venture company between Cipla and Quality Chemicals of Uganda, majority owned by the former. The company operates a WHO-approved

32 EAC Regional Pharmaceutical Manufacturing Plan of Action (2017 -2027)

facility for production of antimalarials, antiretrovirals and hepatitis medicines. The plant supplies the Ugandan market and exports to various markets in Sub-Saharan Africa, including Cameroon, Rwanda, Ghana, Zimbabwe and Zambia.

Abacus parenteral drugs limited is a USD 30 million investment focusing on producing small and large volume parenterals for domestic and export market, it is one of the largest such facility in the region. Rene Industries mainly produces medicines for treating infectious diseases, anti-bacterial drugs, anti-protozoals, anti-fungals, painkillers, and cough and cold medicines. The company exports to Rwanda, Burundi, South Sudan and the Democratic Republic of the Congo. According to the National Drug Authority, the local manufacturers have a total of 173 registered products in the market. The main exports destinations for local manufacturers are Eswatini, Rwanda, Zambia, D R Congo and South Sudan. Local distribution of pharmaceutical products is in the hands of around 55 local pharmaceutical distributors, and of these 10 pharmaceutical distributors control approximately 85 percent of the market.

The government has been making efforts to promote local production, for example, in 2017, the verification fee was increased from 2 percent to 12 percent on 37 selected medicines that are locally manufactured[33]. This conferred a price advantage to locally produced medicines over imports and domestic demand increased with local manufacturers reporting a rise on utilisation of installed capacity from under 50 percent to over 70 percent for selected production lines.

According to the Uganda Investment Authority, there is strong investment potential to produce cotton-based consumables in Uganda including wadding, gauze, bandages and surgical cotton wool. Raw materials can be sourced locally given Uganda's comparative advantage in cotton production.

Pharmaceutical manufacturing in Zimbabwe

The pharmaceutical market in Zimbabwe was valued at USD 367.8 million in 2020. According to the Medicines Control Authority of Zimbabwe, there are nine domestic drugmakers in the country namely; CAPS Pharmaceuticals, Varichem Pharmaceuticals, Pharmanova, Datlabs, Plus Five Pharmaceuticals, ZimPharm, Graniteside and Gulf Drug whilst Ecomed manufactures veterinary products. Currently, the country is dependent on imports for around 90 percent of its medicines and local drugmakers are only producing at 20 percent of their total capacity[34]. The Medicines Control Authority of Zimbabwe (MCAZ) is responsible for the registration and licensing of human and veterinary drugs and certain medical devices. The authority's Zimbabwe Regional Medicines Control Laboratory is used as a national quality control laboratory for medicines and medical devices. The National Pharmaceutical Company of Zimbabwe, the national drug supplier in the country, is tasked with providing medicines to all government hospitals and clinics.

Pharmaceutical companies in Zimbabwe are classified as small to medium enterprises with annual sales of less than USD 15 million. The industry has a wide product portfolio which ranges from 3 to 129 products of different dosage forms. The local manufacturers produce USD 31.5 million worth of products while the remaining are imports. Exports of pharmaceutical products constituted about USD 3 million in 2019[35].

33 Fitch Solutions, Uganda Pharmaceuticals and Healthcare report, 2022
34 Fitch Solutions, Zimbabwe Pharmaceuticals and Healthcare report, 2022
35 Pharmaceutical Manufacturing Strategy in Zimbabwe (2021 - 2025)

In June 2021, Zimbabwe launched the Pharmaceutical Manufacturing Strategy: 2021-2025, with the aim of boosting local production of drugs. The strategy is anchored on key pillars namely research and development; expedited registration processes of new pharmaceutical products; export orientation; compliance with Good Manufacturing Practices; and state support. The strategy will be supported by private sector and public investments amounting to USD 45 million over the next five years, while a Pharmaceutical Sector Revitalisation Fund will also be set up to provide funding for the development of the sector.

Drug manufacturing has been negatively affected in recent years by high levels of inflation and the lack of foreign currency has made importing active pharmaceutical ingredients (APIs) prohibitively expensive, limiting the domestic industry, despite existing demand. Manufacturers in Zimbabwe have to pay value added tax (VAT) on other imported raw materials at point of entry. The Zimbabwe Revenue Authority (ZIMRA) then refunds the VAT after 60 days. This effectively means that the manufacturers have to use borrowed money to pay VAT and have to pay interest on the borrowed funds, while the funds are repaid by the government without interest.

Varichem Pharmaceuticals is a privately owned Zimbabwean company established in 1985. It manufactures and markets a wide range of generic pharmaceutical products for a number of areas including infantile diarrhoea, pain management, cardiovascular, dermatology, diabetes, rheumatology, anti-infectives and gastroenterology. In addition to supplying the local market, Varichem exports its products to Malawi, Botswana, South Africa, Namibia, Lesotho and Eswatini. The company had achieved World Health Organisation (WHO) Prequalification (PQ) for an ARV but that PQ status has since lapsed.

Mauritius promoting investments in health technologies

The pharmaceutical market in Mauritius was valued USD 234.1 million in 2020 with spending on medicines per capita being the highest in the region at USD 184 a year. In Mauritius, the regulation of pharmaceuticals is carried out by the Medicines Regulatory Authority (MRA), which is part of the Ministry of Health. The major categories of pharmaceutical products imported regularly by Mauritius include anti-infectives, vaccines and medicines for non-communicable diseases among others. Private wholesalers import about 75 percent of the total pharmaceutical products in Mauritius, while the health ministry, which tends to purchase mainly generic medicines, imports the other 25 percent by value[36].

In February 2021, India and Mauritius signed the Comprehensive Economic Cooperation and Partnership Agreement (CECPA), which came into force in April 2021 and includes a list of goods including medical and surgical equipment. The Mauritian government offers a tax holiday of eight years, 3 percent corporate tax on profits derived from exports, investment tax credit for investment in high-tech manufacturing, and air- and sea-freight rebates on exports for new companies engaged in the production of pharmaceuticals. Pharmaceutical products are subject to price control in Mauritius under the maximum mark-up regulations made under the Consumer Protection (Price and Supplies Control) Act 1998. The maximum mark-up applicable to pharmaceutical products is currently 35 percent on landed cost. In addition, local pharmaceutical manufacturers benefit from a margin of preference of 30 percent on their locally manufactured goods.

36 Fitch Solutions, Mauritius Pharmaceuticals and Healthcare Report, 2021

Box 3. Highlights of the sector incentives

- Premium investor certificate to all companies engaged in the manufacture of pharmaceuticals and medical devices
- Full tax credit on the costs of acquisition of patents
- Three percent corporation tax on profits derived from exports of goods (after 8-year corporate tax holiday)
- VAT on raw materials is payable at customs clearance but reimbursable on exports
- Refund of 60 percent on Air Freight Cost for export to Africa (including Madagascar), Australia, Canada, Europe, Japan, Middle East Countries and USA (until June 2022)
- Refund of 25 percent on Basic Freight Cost (the maximum of USD 300 per 20T – feet container and USD 600 per 40T -feet container) in 20 countries in Africa

Currently, there is no active pharmaceutical production in Mauritius as the two plants that were in operation have shut down. There are seven medical device manufacturers exporting mainly to Europe, USA and Asia.

A nascent biotech industry and research culture is growing in the country with 14 biotech companies having operations related to the health sector as of March 2019. According to the Board of Investment of Mauritius, the biotech industry contributed around USD 100mn to the economy in 2016 and has created more than 1,300 jobs. Over the last three years, the sector had attracted foreign direct investment amounting to USD 28.7mn

Further, tax Incentives for R&D include an accelerated capital allowance of 50 percent on capital expenditure incurred on R&D and a 200 percent tax deduction in relation to qualifying expenditures on R&D, which is applicable for five income years from 2017 to 2022. The Mauritius Investment Corporation has prioritised investing in the production of pharmaceuticals, medical devices and personal protective equipment through a public private partnership model.

Pharmaceutical manufacturing in Tunisia: a well-established sector with a growing export share

The market was valued at USD 630 million in 2020 with the sector growing by more than 45 percent over the 2014 - 2018 period and share of exports increasing from 10 percent to more than 17 percent over the same period[37]. In 2018, the sector had around 120 companies operating across all activities in the value chain, including more than 33 in the production of medicines with the sector accounting for almost 2 percent of the GDP. Sanofi was the first international pharmaceutical group to invest in the country and has more than 400 employees producing more than 30 million units per year. Pfizer is one of the most dominant multinational manufacturers in Tunisia, and the company's national manufacturing unit was launched as a joint venture with SIPHAT in 1998. The facility is currently responsible for the local manufacture of 19 products.

TERIAK Laboratory, a subsidiary of the KILANI group, has been a major player in the Tunisian pharmaceutical industry since 1996. The company currently employs more than 500 people in over 3

37 Tunisia Investment Authority, A Pharmaceutical Sector Presentation,

sites, including two in Tunisia and one in Douala, Cameroon. The company, has a number of contract manufacturing agreements with leading multinational pharmaceutical companies, including Sanofi, Abbott, Novartis, GlaxoSmithKline and Roche. UNIMED laboratories manufacture, develop and market a wide range of eye drops and injectables for pharmacies and hospitals and employs more than 650 people. Teriak Laboratories, the Society of Pharmaceutical Industries of Tunisia (SIPHAT) and Opalia Pharma, are the dominant generic drugmakers in the Tunisian pharmaceutical landscape[38].

The pharmaceutical sector benefits from a rich ecosystem that promotes research & development, scientific progress and the development of clusters. The sector is experiencing a strong mobilization of public and private players in particular through the implementation of the pharmaceutical pact which aims to improve the national ecosystem in terms of infrastructure, governance, training and investment. Tunisia has a relatively well-established clinical trials system compared with many of its African peers. The environment is well prepared for clinical trials in terms of regulation, expertise and resources.

Pharmaceutical manufacturing in Zambia

The market was valued at USD 356 million in 2020 with 10 manufacturers in active production. The principal legislation in the legal framework for the manufacture of pharmaceuticals in the country is the Medicines and Allied Substances Act No. 3 of 2013. It establishes the Zambia Medicines Regulatory Authority (ZAMRA) as the statutory national regulatory body for medicines. ZAMRA is vested with authority to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances.

The country has a nascent generic manufacturing industry comprising both domestic and foreign players, mainly from India with investment in the sector encouraged by the authorities. NRB Pharma has invested USD 12 million in a production plant while Kingpharm, Zambia recently opened a USD 30 million plant, the output of which is destined for both local and international market. Kingpharm Zambia and Zambia-China Economic and Trade Corporation Zone reportedly each invested USD 15 million in the facility, which produces a range of medicines vital for the domestic and regional markets and will employ 200 people.

According to Zambia Manufacturers' Association, the charging of excise duty on raw materials and other production inputs, whilst there is no import duty on final pharmaceutical products is a disincentive to local manufacturing. Therefore, trading and distribution become easier for Zambia pharmaceutical companies as they would rather import and distribute rather than manufacture locally. Other challenges facing the sector include limited investment in infrastructure, lack of appropriately trained human resource and inadequate funding for research and development (PMRC,2022). Despite the challenges, opportunities exist in the sector for import substitution and intraregional trade notably within the neighbouring countries such as D R Congo. The sector players are also calling on the government to support R&D and commercialisation of the Indigenous Knowledge.

The government is providing fiscal and non-fiscal incentives in order to spur investments in the sector. For example, there is zero tax on dividends and on profits for a period of five years after commencement of operations as well as zero import duty on capital equipment and machinery.

38 Fitch Solutions, Tunisia Pharmaceuticals and Healthcare Report, 2022

Pharmaceutical manufacturing in Madagascar: a strong focus on developing herbal based medicinal products

Madagascar like the other countries in the region is overly dependent on imports for pharmaceuticals and other medical supplies. The main source countries include China, France, India, Switzerland and Germany with Egypt and Mauritius among the suppliers from the COMESA region. The country has three manufacturing facilities namely;

- FARMAD - manufactures generic and herbal based medicines and alcohol-based sanitizers;
- HOMEOPHARMA - manufactures herbal based medicinal products
- PHARMALAGASY – Formerly named OFAFA has been upgraded and modernised by the government. It has capacity to produce 15,000 capsules and 240 bottles per minute. The factory is focusing on generic medicines as well as development and production herbal-based products for treatment of COVID-19 and other diseases39. The company has set a target of producing up to 12 herbal-based products within the next three years for the treatment of chronic diseases such as diabetes, asthma, malaria among others.

The country has prioritised pharmaceutical manufacturing in its industrialisation agenda and has put in place a National Pharmaceutical Policy (PPN) and a National Pharmaceutical Master Plan (PDPN). The strategic axis (pillar) 4 of the PDPN 'Research and therapeutic innovation adapted to the needs of the population' focuses on; promotion and support to local pharmaceutical industries; promotion of traditional medicine as well as the development of research that promotes the Malagasy pharmacopoeia; and strengthening collaboration with institutions producing traditional pharmacopoeia

The regulation of pharmaceuticals and other health products intended for sale is under the national pharmaceutical regulatory authority, Madagascar Medicines Agency while the authorizations for the import and customs clearance of products intended for national health programs as well as donations are issued by the Department of Pharmacy, Laboratories and Traditional Medicine. The country acknowledges insufficient technical capacity for quality control of vaccines and relies on recognition of the evaluation and quality control carried out by stringent regulatory authorities or the World Health Organization. The country also has limited capacity on the evaluation of the quality/performance of the diagnostic products and medical devices. On medicines procurement, there is currently no preference scheme or agreement established with COMESA member countries for the purchase of locally and/or regionally produced products.

There is need to further support local manufacturing through policy action, for example, raw materials are subject to customs duties while finished pharmaceutical products are exempt from customs duties, this disadvantages local manufacturers over imports.

Pharmaceutical production and supply in Eswatini

The main source countries for pharmaceuticals in Eswatini include South Africa, India, Cyprus, China, USA, UK and Ireland. From the COMESA region the country imports from Kenya and Zimbabwe a

39 The potential of pharmaceutical industry in Madagascar (2020), https://edbm.mg/the-potential-of-pharmaceutical-industry-in-madagascar/

portfolio of products including antidiabetics, antihypertensives, and antibiotics among others. Though there is no local manufacturer in the country, there are plans to establish an ARV manufacturing plant. In this regard, the government has signed an MoU with a local company. Constraints in developing domestic pharmaceutical manufacturing in Eswatini include the high logistics costs which impacts negatively on competitiveness.

The country has put in place appropriate policies to promote the sector that include the National Pharmaceutical Policy & Industrial Development Policy. In addition, Part IV of the Procurement Regulations (2020) puts in place measures to promote Eswatini companies. Specifically, they are given a preference in the evaluation of tenders for goods by adding a specified margin (max 15 percent) to the evaluated price of other tenders who are not eligible for the preference during the financial evaluation. To be recognised as an Eswatini company, at least 60 percent of the controlling shares must be owned by citizen(s).

The Medicines and Related Substances Control Act allows for the establishment of a Medicines Regulatory Authority which will be responsible for the regulation of medicines and medical devices. In the absence of the Authority, the Ministry of Health - Medicines Regulatory Unit is currently performing this function. During the COVID-19 pandemic, the country experienced supply chain disruption which was exacerbated by lack of local production capacity. Institutions such as the local university started producing hand sanitizer and in addition, textile companies started producing different types of protective clothing to contain the transmission of COVID -19.

4.3 Value Chain Analysis on selected COVID-19 supplies

This section provides an analysis of the value chains for selected COVID-19 supplies including pharmaceuticals, medical oxygen and vaccines. The value chain for diagnostics is described under other medical supplies section.

4.3.1 Pharmaceutical manufacturing

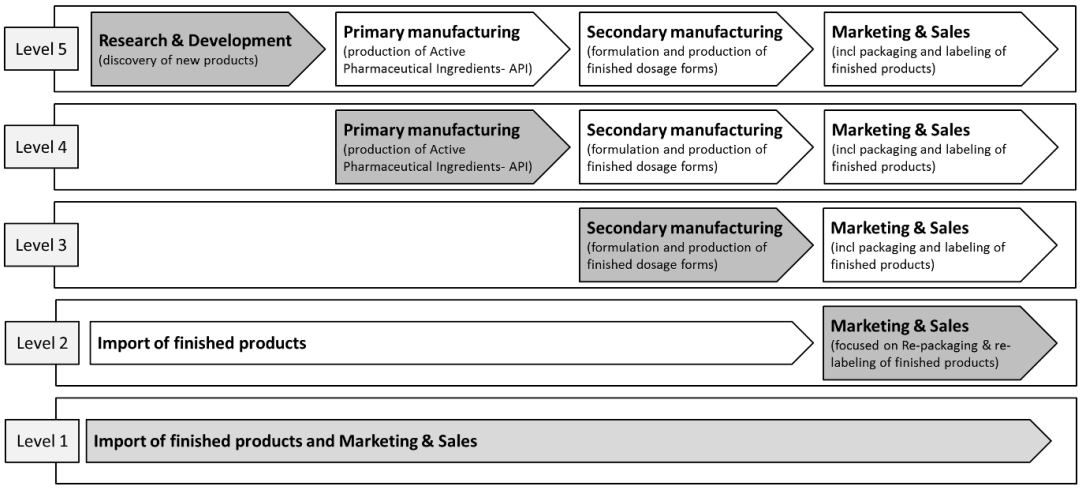
The pharmaceutical manufacturers in the region produce simple generic formulations instead of higher value medicinal products. While a number of companies are now differentiating themselves by producing branded generics especially for over-the-counter medications (OTC), the majority of firms are producing multisource generic products, largely unbranded, that are less expensive than innovator or branded products. Moreover, most local firms compete with each other in the same market segments as they have similar product portfolios with a focus on anti-infectives, analgesics, vitamins, cough and cold preparations.

The market dominance of imports mainly from India and China is partly attributed to a host of factors that disadvantages pharmaceutical manufacturing in the region. These include; scale, expensive asset base coupled with older technology, higher financing costs plus lack of integration with active pharmaceutical ingredient suppliers. Other challenges include lack of appropriate skills mix and unreliable support infrastructure such as electricity, water and logistics. Local manufacturers import active pharmaceutical ingredients (APIs), excipients, plant equipment and machinery from India and China while analytical equipment is sourced from high-income countries.

Figure 7 illustrates the pharmaceutical value chain. The majority of the players in Africa, COMESA

included, are predominantly at Level 1**,** with manufacturing activities largely confined to Levels 2 and 3. Local firms are mainly producing finished pharmaceutical products (FPPs) rather than manufacturing active pharmaceutical ingredients. APIs are the key input for manufacturing FPPs and a substantial cost factor in production of up to 80 percent. This places local manufacturers at a disadvantage over imports as they have no cost control of the APIs.

Figure 7 . Pharmaceutical Value Chain



Source: EAC Regional Pharmaceutical Manufacturing Plan of Action (2017 -2027)

An upgrade of local manufacturing to higher-value medicinal products is currently hampered by lack of technical expertise and access to finance. In particular, there is a gap on product development and formulation expertise required to upgrade the dosage form portfolio. With regard to finance, firms are challenged by lack of appropriate and affordable finance. At the moment, financing options are limited to short term loans with high interest rates. Further, local manufacturers struggle to adhere and comply with internationally recognised Good Manufacturing Practices such as WHO GMP.

Governments across the region have put in place incentive frameworks to promote local pharmaceutical production. These include, according a price preference of up to 15 percent to local manufacturers in public tenders. In Ethiopia for example, the government offers a 25 percent price preference to local manufacturers in addition to 30 percent advance payment on purchases. The balance of 70 percent is also pre-financed through a loan facility set up by a state bank (GOE,2015). Other incentives include duty free imports on equipment, machinery and other inputs for production.

Despite the existing incentives, local manufacturers across the region complain of being disadvantaged against imports. They indicate that the current preference margin of 15 percent which is offered by most public procurement agencies is not sufficient to confer competitive advantage. Further, the importation of finished pharmaceuticals with a duty rate of zero percent means that the value addition of local production is not taken into account. There is therefore a need to recognize investment made in pharmaceutical production and review the tariff structure to sustain local industries in segments where they have comparative advantage and adequate capacity to supply the market. For example, in the East African Community, the Federation of East African Pharmaceutical Manufacturers (FEAPM) has

proposed the introduction of a common external tariff (CET) of 25 percent for selected pharmaceuticals where the region has capacity to produce in sufficient quantity. Pharmaceutical manufacturers argue that their investments create direct and indirect jobs along the value chain and promote establishment of support industries and services, which should be taken into account in the tariff structure.

4.3.2 Production and supply of medical oxygen

Oxygen is a high-return, lifesaving treatment for COVID-19 and a hallmark of functional health systems. It is an essential medicine for the treatment of many conditions affecting new-borns, children and adults, including pneumonia. But, even before the health crisis, access to safe and affordable oxygen in low- and middle-income countries (LMICs) was low. The pandemic has exacerbated this situation, leading to many preventable deaths. Challenges for accessing oxygen in LMICs are multiple and can range from complex logistics with oxygen supply not always reaching the destination on time, to the need for good infrastructure and upkeep for most oxygen systems, or to a lack of market competition in countries resulting in high prices and fragmented access.

In Sub-Saharan Africa, there are two main sources of oxygen: concentrators and cylinders. While concentrators are the cheapest and most scalable way to supply oxygen, they require a functioning infrastructure with reliable power supply as well as regular servicing. In addition, the level of oxygen flow that they can deliver can be insufficient for severely ill patients. However, they may be used to ease demand on cylinders, which can be directed to patients with severe COVID-19. The more expensive cylinders require neither a power source nor costly maintenance. The issue with oxygen supply in Africa is more to do with delayed delivery and limited storage capabilities (mostly stored in cylinders) rather than manufacturing. In fact, almost all African countries have oxygen manufacturing plants or can source it from private sector providers. At the beginning of the pandemic, there were 68 oxygen generating plants, which has now increased to 119 across the continent. There were also 2,600 oxygen concentrators and now there are 6,100, according to WHO Africa (The Lancet, 2021).

In Kenya, cylinders, concentrators and plants are the main sources of oxygen used across health facilities. Cylinders are rented from suppliers, while concentrators are owned by the facilities and plants range from facility-owned to private public partnership (PPP) or Managed Equipment Service (MES). There are five major suppliers of oxygen gases in-country and 47 oxygen plants spread across the country. In Ethiopia, a garment manufacturer that produces oxygen for bleaching purposes aims to provide it to a nearby hospital, reflecting technology spill over. In Uganda, solar-powered oxygen delivery for rural settings has been developed to overcome issues of unreliable power supply. Solar-powered systems can turn ambient air into medical-grade oxygen with battery banks, enabling uninterrupted service through the night and on cloudy days.

Some of the challenges in supply and production of medical oxygen include;

- Quality shortcomings on all sources of supply especially with concentrators and plants, with overdue maintenance schedules.
- Infrastructure such as unreliable supply of electricity and availability of appropriate space for installing plants and concentrators.

- Costs associated with cylinders and supply chain were cited as the key challenges that hinder access of oxygen despite its quality advantages. The supply chain is inefficient with fragmented ordering process; high cost of rental/deposit; depot collection model; and improper storage and handling of cylinders and accessories.
- The plants experience leakages with most not operating optimally due to limited piping and breakdowns. Poor plant or bulk tank maintenance means the production capacity of plants to produce medical grade oxygen (90 percent oxygen) decreases, and in some cases oxygen quality is less than 70 percent oxygen.

4.3.3 Production and supply of vaccines

Though the vaccine manufacturing in Africa is currently nascent, demand is set to more than double in volume over the next decade from approximately 1 billion doses today to over 2.7 billion doses in 2040. By value, excluding future demand for COVID-19 vaccines and most other new vaccines yet to be developed, the public market for vaccines in Africa is expected to reach an estimated USD 3 billion to USD 6 billion by 2040. Already, self-financing countries represent a market of USD 419 million, or one-third of the African vaccine market. The share of self-procuring countries is expected to grow in the next decade as more countries transition from Global Alliance for Vaccines and Immunization (GAVI) support[40].

The market landscape for vaccines is different from the conventional pharmaceuticals. There are a few large manufacturers dominating the market and limited number of bulk purchasers or procurement agencies. In Africa the dominant buyers are UNICEF Supply Division and GAVI, with their procurement decisions being driven by price and WHO prequalification of the product. The regulation of vaccine is more demanding as the market approval is required per lot release and the national regulatory authority must have the technical capacity to undertake the same.

Investing in vaccine production, is both capital and technology intensive requiring complex partnership arrangements on technology transfer and market territorial rights. The high barriers placed by technology acquisition, capital and regulatory requirements coupled with the imperfect market conditions confers investing in vaccine production a unique risk. Only a handful of companies manufacture the drug substance in Africa, typically at small scale, which results in relatively high production costs. Fill-and-finish and package-and-label capacity is better established in the continent, for example, in South Africa, Egypt, and Senegal; more than 10 products are currently filled. In comparison, Asia and Western Europe each have more than 10 established, large-scale vaccine manufacturers, many of which operate across the full value chain, including the higher value-adding steps, and produce high-quality products at low cost (Mckinsey & Company, 2021) .

Figure 8 illustrates the vaccine manufacturing value chain;

40 PAVM Framework for Action, 2022

Figure 8. Vaccine manufacturing value chain

Source: author

In the region only, Vacsera in Egypt and Pasteur Institut of Tunisia have limited volume drug substance manufacturing, fill-finish, along with packaging and distribution. However, as a result of the COVID-19 pandemic, Kenya, Rwanda and Uganda have announced plans to set up vaccine manufacturing plants. Kenya has signed a memorandum of understanding with Moderna for a USD 500 million investment in a drug substance vaccine manufacturing plant[41]. Minapharm and BioGeneric, from Egypt through a partnership with Russian Direct Investment Fund (RDIF) intend to set up drug substance production plants for Sputnik[42].

The steep challenge around access to COVID-19 vaccines has triggered capacity creation impetus across national, regional and continental levels. A number of countries in the continent have announced plans to set up fill and finish and then progressively move up the value chain. The African Union and African CDC have launched the Partnerships for African Vaccine Manufacturing (PAVM) framework to focus on overall roadmap, strategy and execution support for achieving the target of 60 percent on-continent manufacturing by 2040. The key pillars of the strategy include: Access to finance; Technology transfer and IP; Regulatory strengthening; R&D and talent development; Market design and demand intelligence and coordination[43].

The PAVM framework for action prioritizes the manufacturing of vaccines for 22 diseases identified as critical. These comprise vaccines for ten legacy diseases (including Tuberculosis, Hepatitis B, and Measles), which are typically high-volume and can offer economies of scale; six expanding diseases that typically do not yet have commoditized vaccines or have relatively higher-priced vaccines (including key pandemic and endemic diseases for which vaccines are needed such as HIV, Malaria, and COVID-19); and six outbreak diseases (including Ebola). A focus on these diseases would address the continent's pressing patient needs through vaccines that would be feasible and attractive to manufacture. Some of the prioritized diseases have vaccines that have already been developed, and so the need is for local production and access. Others have vaccines still under development, which could be brought to fruition and subsequently produced on the continent.

Further, the framework for action has also prioritized seven vaccine manufacturing technologies to provide sufficient flexibility to produce the vaccines. These include traditional technologies such as live attenuated virus technologies, which will be critical in manufacturing vaccines with high demand, and novel technologies such as mRNA, which are likely to grow in scale as the science and investment supporting the technologies advance.

The COMESA region should therefore align its interventions to the PAVM framework for action. Further,

41 https://www.health.go.ke/kenya-signs-mou-with-moderna-to-establish-its-first-mrna-manufacturing-facility-in-africa/

42 Market Analysis to Establish a Fill and-Finish Vaccine Plant in Ghana, GIZ, 2021

43 PAVM Framework for Action, (2022)

the region should leverage on the integrating market to make vaccine production viable through initiation of pooled procurement and regulatory harmonisation.

4.3.4 Other medical supplies

The value chains for the other medical supplies in the region are not as developed as that of pharmaceuticals. This section briefly, describes diagnostics and medical device value chains in the region. The COMESA region imports more than 90 percent of medical diagnostics and devices owing to lack of existing capacity to manufacture the same. The reasons for this include lack of access to technology and know-how; unavailability of raw materials and other support industries; and poorly developed regulatory environment which discourages investment from global players owing to reputational risk. There is limited capacity in the region to produce rapid diagnostics in the region with countries such as Kenya, Uganda, Egypt and Mauritius having packaging plants for the same. The companies in these countries have started off with packaging and assembling rapid diagnostic kits with the intention of moving up the value chain. Figure 9 illustrates a typical point of care diagnostics value chain;

Figure 9. Point of care diagnostics value chain

Source: Adapted from PLOS Neglected Tropical Diseases

Revital Healthcare Ltd, a Kenyan medical supply manufacturer, is one of 25 auto-disable syringe manufacturers prequalified by the World Health Organization (WHO). Revital is currently the only WHO prequalified manufacturer for vaccine syringes in Africa that are contracted by various international programs aimed at assisting low and middle-income countries (LMIC's) for syringe supply for 2022. Over 300 million units of the 0.5ml vaccine syringes will be exported to various countries by Revital in 2022. A further, 50 million units of 2 ml syringes will be supplied to India. The company manufactures over 45 medical devices ranging from various syringes, Rapid Covid Antigen test kits, Rapid Malaria test kits, oxygen related products, PPE kits, surgical face masks, Viral Transport Medium kits amongst others. The company supplies its products to over 20 countries in Africa, Europe and Asia as well as international procurement agencies. According to the company, the key challenges include varied regulatory requirements, lack of appropriate skills and access to raw materials which have to be imported.

The production of medical devices requires multi-disciplinary approach involving medical, biotechnology and engineering professionals. Across the region, there exists skills gaps and product development expertise with poor linkages between the academia and industry. As a result, the development of medical devices gets stuck at prototype stage with innovators not able to progress to commercialisation and scale up. This challenge became apparent during the pandemic with innovators developing ventilators, but they were not able to scale up beyond the prototype due to lack of financing, components and spare parts as well as capacity of the national regulator to assess and grant market

approval. This is despite the fact that there is an acute shortage of ventilators across Africa. A report from WHO indicates that fewer than 2,000 working ventilators exist in 41 African countries to serve hundreds of millions of people in public hospitals, compared with more than 170,000 in United States. en countries in Africa have no ventilators at all (Stein F, Perry M, Banda G, et al., 2020).

4.4 Summary of constraints and drivers

The integrating regional market in COMESA presents both constraints and drivers for production of COVID-19 supplies and are summarised below;

Constraints;

i) All major inputs such as APIs, excipients and primary packaging materials are imported. To obtain competitive prices buyers have to purchase large quantities which are not supported by current local demand of finished products.

ii) Machinery and equipment are wholly imported and this poses its own challenges with regards to sourcing and maintenance. In addition, the imported machinery and equipment are subject to value added tax (VAT) in some countries while for others, the process of getting waivers on duty is bureaucratic and not applied consistently.

iii) The scale of production is relatively small, hence higher unit costs. This is further exacerbated by high cost and unreliable supply of utilities (electricity, water, transport).

iv) Local manufacturers tend to focus on producing similar products mainly OTCs and a narrow range of essential medicines. This results in stiff competition for a small market segment whilst leaving a huge section to imports.

v) Local manufacturers struggle to meet and comply to WHO GMP, this is due to lack of appropriate financing to upgrade facilities as well as relevant skills. Further very few local companies are WHO GMP PQ, the majority are therefore unable to participate in international tenders funded by the Global Fund and other partners.

vi) Inadequate supply of appropriate skills mix within the local market. This means expatriates for specific skills set have to be sourced from abroad and this comes with additional costs.

vii) Local manufacturers face challenges exporting to the regional market due to differences in regulatory regimes, limited harmonised product standards and fragmented supply chain systems. In addition, local manufacturers interviewed mentioned the implementation of stringent regulatory measures even where local capacity does not exist. For example, the requirement of bioequivalence studies for generics of well-known molecules that have been in the market for decades.

The COMESA Business Council highlighted product standards, border procedures and national regulatory environment as the top three constraints to intra-regional trade.

Drivers;

i) The young, growing population with an expanding middle class, the increasing non-communicable disease (NCD) burden and continued prevalence of infectious diseases, will further increase the opportunities for local manufacturers on the pharmaceutical and medical supplies market.

ii) The supply chain disruptions of COVID-19 pandemic have made countries to priorities and fast track strategies for promoting local production of pharmaceuticals at national and regional level.

iii) Continental and regional initiatives to harmonise regulatory regimes to allow for faster market entry and improve access to lifesaving commodities.

iv) The Free Trade Area (FTA) status of the COMESA region and the continued efforts to address existing and/or emerging non-tariff barriers.

The COMESA Business Council highlighted skills and technology, affordable and reliable energy and trade infrastructure as the top three drivers for intra-regional trade.

Table 6 highlights the Strengths, Weakness, Opportunities and Threats (SWOT) for pharmaceutical and medical supplies production in the region;

Table 6 . A SWOT analysis for pharmaceutical and medical supplies production

STRENGTHS	WEAKNESSES
• Young and growing population of 583 million with an expanding middle class (2020). • Existing political context and will to strengthen local production. • USD 5.6 billion pharmaceutical spending in 2020. • A strengthening regulatory capacity and enforcement within the context of regulatory harmonization initiative. • Massive investments in infrastructure (energy, water & transport) in the region. • COMESA is designated as a Free Trade Area which facilitates intra-regional trade • Existence of WHO GMP compliant facilities as well WHO prequalified facilities e.g., production sites, laboratories	• Relatively high cost and unreliable supply of utilities e.g electricity, water. • Over reliance on imports of APIs and other production inputs e.g equipment, machinery, primary packaging and excipients. • Insufficient HR base and skills mix for the pharmaceuticals and medical supplies sectors. • Weak R&D base (institutions, resources, capacities). • Insufficient incentives and policies to promote investment. • Ineffective and inadequate preferential treatment of locally produced pharmaceuticals in government procurement programs. • Lack of access to reliable market data • Lack of access to appropriate financing • Lack of support service infrastructure such as Bio-equivalence (BE) centres.

OPPORTUNITIES	THREATS
• Momentum of continental, regional and national initiatives to promote local pharmaceutical and medical supplies production particularly within the context of the COVID-19 pandemic. • An increasing budgetary allocation to the health sector in the region. • Extension on the use of public health related WTO TRIPS flexibilities to 2033. • Existing pharmaceutical production base and enabling regulatory environment. • A nascent medical devices and diagnostics sector in the region. • Larger market in the field of growing NCDs burden and the continued high prevalence of infectious diseases. • Herbal medicinal products as a market niche for health and wellness.	• Competition from cheap imports from India and China. • Presence of sub-standard, spurious, falsely labelled, falsified and counterfeit products in the market. • Poor enforcement by regulatory authorities leading to non-GMP compliant manufacturers actively producing for the region. • Negative perception of locally produced products. • Emigration of qualified and experienced personnel. • Fragmented and unregulated distribution systems.

5. Opportunities for Investments and Policy Actions

Based on the study findings and interactions with key stakeholders the following opportunities for investments (along the value chains) have been identified and summarised in table 7;

Table 7 . Opportunities for investments

Product category	Potential investments	Comments
i) Pharmaceuticals	Development of advanced formulations Expanding product portfolios beyond essential medicines list Production of selected APIs and excipients Investing in international GMP standards production facilities and WHO Prequalified facilities.	Countries with established local production capacity could promote manufacture of advanced formulations while those at nascency should focus on building capacity for essential medicines production
ii) Vaccines	Investment in routine, non-routine, neglected diseases and disease outbreak vaccines. Opportunities exist in the region along the whole value chain from drug substance manufacturing, formulation to fill and finish.	This will require a regional approach to create economies of scale to make the investments viable
iii) Medical Oxygen	Investments in oxygen plants, oxygen concentrators and oxygen cylinders	All the countries should build capacity to ensure improved access to medical oxygen in all health facilities given its importance in public health emergencies
iv) Diagnostics	Investments in point of care diagnostics including rapid test kits as well ELISA and PCR technologies. Production of reagents and sample carrier media.	Strengthen local R&D capacity to support product development. Support diagnostics distribution companies to move up the value chain by initially starting with assembling and packaging of rapid test kit components and production of carrier media.
V) Medical Devices	Investment in medical devices to aid in diagnosis and treatment of all diseases. The region relies on imports on all medical devices.	Support prototype development, commercialisation and scale up. This will require both national and regional approach.

i)	Other medical supplies		Investments in production of medical grade garments, sample collection materials, needles, syringes, cannulas etc. Textiles and plastic companies should be supported to retrofit their production facilities or invest in new production lines to manufacture medical supplies within their area of competence.	Promote cross linkages among value chains such as medical with textiles and plastic value chains.
ii)	Herbal and medicinal products		Investment in quality assured herbal and natural products for domestic and export market. Increasing demand for natural products as starting materials, active ingredients, excipients nutraceuticals and cosmetics globally.	Support R&D, regulation, commercialisation and scale up for herbal and natural products.
iii)	Support industries and services		Opportunities exist in packaging, logistics and advanced analytical services such as Bioequivalence, formulation development and contract research organisations	A regional approach should be considered for the establishment of a Bioequivalence Centre.

In order to promote investments in the product categories listed in Table 7 above, there is need for policy actions targeting specific sections along the value chain. A suitable incentive framework will need to be put in place at regional and national level as applicable. The regional incentives should leverage on the existing free trade area. For example, preferential treatment should be extended by all Member States to regional manufacturers in public tenders for medical products. This will confer an advantage to regional manufacturers over imports from outside COMESA. The national policies and laws on public procurement will need to be amended to allow for regional preferential treatment. In order to make the production of vaccines viable in the region, the concept of pooled procurement should be considered and operationalised.

The pharmaceutical manufacturers interviewed mentioned lack of access to appropriate financing while the finance institutions on the other hand indicated the need to understand the sector better. There is need, therefore to strengthen exchange between financial institutions and local manufacturers so that the operations and risk profiles of the latter can be better understood.

Further, in order to encourage the setting up of production facilities in the region there is need to review the common external tariff (CET) for medical products. For example, the CET for selected products, which the region has capacity to produce in sufficient quantity and acceptable quality should be increased from the current zero percent to a higher figure that will be jointly agreed by the Member States. At the regional level there is need to harmonise the regulation and standards applicable to all categories of medical products. This will enhance intraregional trade and make the region attractive to investors who want to set up production facilities. For diagnostics and medical devices, a regional approach should be taken to promote research and development, innovation and commercialisation. Access to appropriate financing for the manufacture of medical products should be promoted by

encouraging financial institutions to develop special packages that recognise the unique characteristics of the sector.

Some of the policy actions for implementation at the national level include developing and implementing incentives for the manufacture of finished products, APIs and other medical products. Each of these products would require a unique set of incentives. For example, the production of APIs presents a greater business risk than finished products, therefore the incentives should take this into consideration through granting of longer tax holidays. The production of vaccines would require advance market commitments by the host government and possibly including other Member States. The region is at nascency stage in the production of diagnostics and medical devices. Therefore, policy actions should be geared towards promoting research and development (R&D), innovation, incubation and commercialisation as development of prerequisite skills mix.

The region should promote the establishment of specialised pharmaceuticals and medical products parks. The specialised parks will provide shared infrastructure including reliable supply of utilities and delivery of government services through a one-stop-shop concept. These initiatives are likely to attract investments as they lower the initial capital outlays. The Member States should put in place policies that promote investments in herbal and medicinal products targeting agronomic practices, collection and aggregation, regulation and processing.

Last but not least, efforts should be made to bring a convergence of public health needs, which focuses on sourcing medical products at the cheapest price (imports) and industrial policy needs which focuses on job creation through local manufacture. This should be done through a policy coherence approach involving health, trade and industrialisation sectors.

6 Lessons from other Countries and Regions

6.1 Lessons from the Regional Economic Communities

The COMESA region can draw lessons from other Regional Economic Communities in the continent that have taken deliberate steps in promoting pharmaceutical and medical products manufacture. This section highlights some of the good practice examples which can serve as lessons.

The East African Community (EAC) has put in place programmatic initiatives supporting local pharmaceutical production in partnership with development partners. These include the development and implementation of an EAC Regional Pharmaceutical Manufacturing Plan of Action (EACRPMPOA): 2017-2027. The plan sets four high level targets for the development of the EAC pharmaceutical sector which include: reverse dependency on pharmaceutical imports from outside EAC from more than 70 percent to less than 50 percent; support the expansion of product portfolio of EAC firms to cater for more than 90 percent of disease conditions; at least 50 percent of purchases by EAC national medicines procurement agencies is sourced from EAC pharmaceutical manufacturers; and at least five companies to produce more advanced pharmaceutical formulations such as delayed release formulations, small volume injectables, double layered tablets, among others. The plan is being implemented within a framework of six pillars that promote investments and firm level competitiveness, strengthening of regulation, development of appropriate skills, use of public health-related World Trade Organisation

Trade Related aspects of Intellectual Property Rights (WTO TRIPS) flexibilities and mainstreaming research development and innovation within the pharmaceutical industry[44].

Further, the region has put in place an EAC GMP Roadmap Framework that guides the respective regulatory agencies and manufacturers towards GMP compliance. The roadmap proposes rewarding GMP compliant companies through preferential market access across the region. The region is also implementing a medicines regulatory harmonization (MRH) programme with the support of a consortium of partners including the World Bank, WHO and Bill and Melinda Gates Foundation among others[45]. Through the EAC MRH, the region has developed harmonised guidelines for medicines registration and GMP inspections. Joint medicines registration evaluation and inspections shortening the time to market for medicinal products across the region. In an effort to promote local production, the region has identified eight molecules in which there exists local capacity to manufacture in sufficient quantity and acceptable quality to be accorded preferential treatment. The local manufacturers have established an apex regional advocacy platform, the Federation of East African Pharmaceutical Manufacturers (FEAPM).

The Southern Africa Development Community (SADC) is also implementing a medicines regulatory harmonization project with the support of the World Bank and other partners. Through the SADC MRH/ZAZIBONA initiative, 32 joint assessment sessions and 44 manufacturing sites have been jointly inspected. Further, the region is implementing a SADC Pooled Procurement Service (SPPS) with MSD, Tanzania having been designated the coordinating agency for the initiative[46]. The region has also developed the SADC Pharmaceutical Business Plan: 2015 -2019.

The West African Health Organisation (WAHO) in collaboration with partners has put in place several measures aimed at improving local production in the region. These include:

- Development and launch of ECOWAS Regional Pharmaceutical Plan (ERPP)47;
- West Africa Medicines Registration Harmonization programme;
- The ECOWAS Good Manufacturing Practice (GMP) Roadmap initiative;
- The ECOWAS Trade Related Aspects of Intellectual Property Rights (TRIPs) Policy and Guidelines;
- High level advocacy for implementation of incentives aimed at growing the nascent local pharmaceutical industry.

The West Africa Medicines Registration Harmonization Programme whilst improving access to quality lifesaving medicines will also ease market entry of local manufacturers. This will be achieved by putting in place common guidelines and procedures in all the National Medicines Regulatory Authorities. In addition, regulatory capacity across the region will be enhanced. The programme is implemented with support from a consortium of partners including the World Bank, WHO, Bill and Melinda Gates Foundation and New Partnerships for Africa's Development (NEPAD). The objective of the ECOWAS GMP Roadmap initiative is to establish a strong pharmaceutical manufacturing industry in the region by

44 EAC Regional Pharmaceutical Manufacturing Plan of Action: 2017 -2027
45 https://www.eac.int/mrh
46 SADC MRH Presentation, 2021
47 https://www.unido.org/sites/default/files/2016-01/ECOWAS_Regional_Pharmaceutical_Plan_0.pdf

supporting manufacturers to attain WHO GMP and other international standards.

The pharmaceutical manufacturers in the region have established the West African Pharmaceutical Manufacturers' Association (WAPMA) in order to strengthen their lobby and advocacy. WAPMA was established in 2005 and currently has membership of 200 companies drawn mainly from Nigeria, Ghana, Cote d'Ivore, Togo and Benin. The association seeks to promote pharmaceutical manufacturing in West Africa by creating favorable economic, regulatory and political environment. Notably, WAPMA has been lobbying for application of Common External Tariffs (CET) regime for selected medicines imported into ECOWAS.

The COMESA region can therefore draw lessons from EAC, SADC and ECOWAS to inform the design of appropriate interventions to promote the development of pharmaceutical and medical supplies sector.

6.2 Lessons from India and Bangladesh

India Introduced inward looking trade and investment policies ensuring import substitution with a mix of high import duties and exports subsidies. The country adopted an IP protection strategy that favoured reverse engineering and growth of generic industry. Today India is among the top 20 pharmaceutical exporting countries in the world. Exports to some 200 countries including to highly regulated markets and the industry is growing at an annual rate of 10 percent while exports are growing at 20 percent. Provides employment to 450,000 people and has contributed immensely to creating a rich talent pool of various skills mix[48] .

There are pharmaceutical manufacturing-related and R&D parks or clusters supported by state and Central Government incentive programmes. The main initiative in this area took place in the 1970s with the setting up of a chemical complex in Ankleshwar in Gujarat. Several multinational and domestic companies set up API and formulation facilities in Ankleshwar. It has become one of the largest chemical complexes in Asia. Jawaharlal Nehru Pharma City was established as a sector-specific Special Economic Zone (SEZ). It features a common water treatment plant, a hazardous waste management facility, an incineration system, a power distribution network, a common solvent recovery plant, as well as providing a variety of services for employees.

Incentives provided in the park include, duty-free import and domestic procurement of capital goods, raw materials, office equipment and other materials. Domestic sales of finished products are allowed on payment of applicable customs duties. There is 100 percent income tax exemption for five years and 50 percent exemption for two following years and exemption from minimum alternate tax (MAT). In addition, there is 100 percent foreign investment automatic approval, various exemptions from finance charges with the state government providing value-added tax exemptions for supplies within the SEZ. The establishment of a second pharma city in Andra Pradesh is being planned and there is interest from industry players including bulk drug (API) manufacturers (WHO, 2017).

The Bangladesh pharmaceutical industry has been ranked second in terms of gross value addition for many years after Readymade Garments (RMGs) and the sector has the potential to top the list. The growth of the industry can be traced back to 1982 when the government introduced a raft of policy measures aimed at promoting local industry. The measures included prohibition of multinationals

48 Wesley, Ronoh (2018) Preparatory Analysis and Investment Packaging for Ghana Pharmaceutical Production. London: DFID

(MNCs) to sell simple formulations and to advertise brands produced through toll manufacturing and introduction of restricted medicines list. As a result, MNCs were incentivized to set up own factories in the country. The share of local production increased from 35 percent to more than 90 percent with more than 170 approved and operating companies in 2013 compared to 80 in 1982. Exports to Asia, Latin America, Africa and to countries with stringent regulatory authorities such as the USA[49] .

In May 2018, the commerce ministry published the National Active Pharmaceutical Ingredients (API) and Laboratory Reagents Production and Export Policy. The aim of the policy was to reduce dependency on import of API, increase local production, diversify export and attract additional USD 1 billion foreign direct investment in the sector. The policy has set a target of achieving self-sufficiency in producing 370 important API molecules necessary for exports. If a producer can manufacture at least three API molecules every year, it will get 75 per cent tax exemption till 2032. Entrepreneurs will also enjoy exemption from paying advance income tax (AIT), value-added tax and VAT deduction at source on purchase and sales of raw materials and spare parts till 2032. Manufacturers will also get duty-free facility in import, priority in getting land allocation at the government's special economic zones and export processing zones[50] .

49 Bangladesh Association of Pharmaceutical Industries, http://www.bapi-bd.com

50 New Age Business (2018). http://www.newagebd.net/article/41935/pharma-ingredient-makers-to-get-corporate-tax-holiday-till2032 [Accessed 11 February. 2019]

7 Conclusions and Recommendations

The findings of the study indicate that the region is overly dependent on imports from outside the region for all product categories. This is more so for diagnostics, medical devices and vaccines. For pharmaceuticals other than vaccines the region has some local production capacity with Egypt, Kenya and Tunisia having well established manufacturing industry. Other countries such as Ethiopia, Uganda, Mauritius, Zambia and Zimbabwe have a nascent but growing industry. Egypt and Kenya dominate pharmaceutical production, import and export in the region. The intraregional trade in pharmaceuticals and other medical products is low and there is potential to grow and substitute imports from outside the region.

The value chain analysis indicates that local manufacturers lose out to imports. This is attributed to a host of factors including reliance on imports for all inputs, relatively high cost of utilities and a policy environment that is driven by public health concerns rather than industrial development. For example, imported finished pharmaceutical products attracts a CET of zero percent while the inputs for manufacturing the same product in country is charged a higher rate. The product portfolio for pharmaceuticals across the region indicates that most manufacturers produce simple formulation with not much differentiation therefore the companies compete on a few product lines. For diagnostics and medical devices, the region has a weak local production capacity due to the lack of the right skills mix and absence of an ecosystem that supports product development, commercialisation and scale up. The companies will need to match their product portfolio with the regional needs and must be competitive with regards to quality, functionality and price amongst other parameters.

At policy level, interventions should be made to improve framework conditions that level the playing field whilst supporting the nascent local industry and promoting regional value chains. The existing constraints that impede regional trade needs to be addressed and preferential treatment extended to include all companies domiciled within the region. The stakeholders interviewed in this study prioritised the need for regulatory harmonisation as well as standards. COMESA and the Member States recognise the challenges in the sector which became more apparent during the COVID-19 owing to the supply chain disruptions. Initiatives have therefore been put in place at global, continental, regional and national level. The proposed recommendations therefore take into consideration the developments in the sector and seeks to leverage on the same.

The following recommendations are proposed for action at regional and national level;

Recommendation 1: Establish a sustainable regional coordination mechanism on promotion of medical products manufacture

The COMESA Secretariat should establish a pharmaceutical and medical products desk to be the focal point for the regional initiatives in the sector. The focal point will be the link between the Secretariat and Member States as well as other relevant actors including the private sector and development partners. In particular, the focal point should work closely with the Pharmaceutical Working Group of the COMESA Business Council.

In addition, a '*regional Health Product Technologies manufacturing strategy and action plan'* to act as a regional road map with time bound goals and milestones which are aimed at reversing the region's overreliance on imports with regards to health product technologies. The strategy should aim at

putting in place interventions that will lead to an increase in intraregional trade. The focus should be on promoting regional value chains in the sector with the comparative advantage of the Member States being taken into consideration.

Further, the region should develop a ***'model policy and incentive framework'*** for adoption by the Member States. The policy should draw best practice and lessons from other regions and adjusted to local context for promoting the manufacture of health product technologies. The policy and incentive framework should take cognisance of the unique characteristics and needs of each stage of the value chain for the selected product categories.

Recommendation 2: Strengthen access and exchange of reliable market information

There is lack of access to reliable market data to inform actionable policy and investment decisions in the region. The stakeholders indicated the need to set up a reliable market information system for accessing data so that opportunities for investment and trade can easily be identified across the region. The COMSTAT is a good starting point and could be further improved to provide a more detailed analysis beyond trade data to include an inventory of potential investment opportunities and estimated market size. A regional medical products market information system should be developed that indicates not only trade data (export, import and intra-regional) but also local production volumes as well as donations. The Secretariat and the pharmaceutical technical working group of the COMESA Business Council should set up a platform that allows local manufacturers to regularly report on their production volumes. For pharmaceuticals the market information system should be able to provide data based on anatomic therapeutic chemical (ATC) classification to enable a better understanding of the market gaps and opportunities.

Recommendation 3: Promote regional harmonisation of medical products regulation and standards

The stakeholders interviewed in the study mentioned as a priority the need to harmonise regulation and standards for medical products across the region in order to facilitate cross border trade. Other Regional Economic Communities (RECs) such as EAC, SADC, ECOWAS and IGAD have already initiated regulatory harmonisation. The COMESA Member States are also members to these RECs and the region could draw lessons and fasttrack the harmonisation process. In addition, the region could leverage on the ongoing continental initiatives related to AMRH, the establishment of the African Medicines Agency (AMA) and the AcFTA. The stakeholders recommended the implementation of mutual recognition agreements by Member States on medical products registration in order to limit delays and lower the cost of doing cross-border trade. On the issue of Bioequivalence (BE), the stakeholders recommended the use of risk-based approach rather than blanket application of the requirement.

Recommendation 4: Review the current tariff structure for pharmaceuticals and medical products

The importation of finished pharmaceuticals at a rate of zero percent while inputs are charged import duty means that the value addition of local production is not taken into account. This discourages local manufacturers or foreign companies from investing in the region, as they do not see any advantage in establishing a manufacturing plant in the region. Local manufacturers argue that their investments create direct and indirect jobs along the value chain and promote establishment of support industries and services. There is a need, therefore, to recognize investment made in pharmaceutical production and review the tariff structure to sustain local industries in segments where they have comparative

advantage and adequate capacity to supply the market. For example, the CET for selected products which the region has capacity to produce in sufficient quantity and acceptable quality should be increased from the current zero percent to a higher figure. In reviewing the tariff structure, the public health consideration and the need to support the development of the nascent industry in the region as well build resilience in local supply should be considered.

Recommendation 5: Strengthen the existing quality infrastructure support services for health product technologies

Product innovation, development and commercialisation in the region is hampered by lack of relevant national product standards to guide market entry. This is further exacerbated by inadequate capacity by the relevant national standard bodies and regulatory authorities. This challenge is more marked with regards to diagnostics, medical devices, personal protective equipment amongst others. In instances where relevant international standards have been domesticated, they are not harmonised across the region this further impedes intraregional trade. There is need therefore to support Member States to strengthen the quality infrastructure with regards to standards, metrology, conformity assessment and accreditation.

Recommendation 6: Promote market shaping and consolidation in the region

The region continues to import products where local capacity exists even as the existing investments underutilise their installed capacity by up to 50 percent. In order for the region to benefit across the full value chain of the various health product technologies there is need for market consolidation for raw materials, intermediates and finished products. For the final products, the region should put in place mechanisms for regional preferential procurement which is currently only applied at national level by most countries. In addition, even though there are WHO prequalified facilities in the region, international procurement agencies continue to source products from outside the region even where narrow marginal price difference of less than 1 percent exists. The region should therefore engage the international procurement agencies to consider procurements for regional use to be sourced from the existing WHO prequalified facilities. The national medicines procurement agencies should adopt flexible multiyear framework contracts with suppliers from the region. Framework contracts ensures business certainty and allows manufacturers to negotiate better prices for inputs due to economies of scale.

In order to encourage investments in vaccines and ensure viability, the region should explore options for structuring consolidated advance market commitments in collaboration with international procurement agencies. The region can draw lessons from SADC and establish an appropriate pooled procurement mechanism for selected products. The private sector should work collaboratively towards establishing viable mechanisms for bulk purchasing of raw materials and intermediates including conducting joint supplier audits and prequalification.

Recommendation 7: Improve access to appropriate financing

The financial institutions in the region should be encouraged to develop customised products for pharmaceuticals and medical supplies sector. Different financial packages are required for the various types of investments be it greenfield, brownfield or operating capital. As a result of the COVID-19 and lessons learnt, international development finance institutions have made available various funding streams for the sector. The region should work closely with these international development finance

institutions along with leading commercial banks to develop appropriate packages for the sector. The region should consider establishing 'A *Pharmaceutical and Medical Products Sector Development Fund'* with favourable lending terms that take into consideration the unique characteristics of the sector. Financing and preferential market access should be tied to investment in quality including GMP compliance.

Recommendation 8: Promote partnerships and investments in provision of industry support services

There is need for the region to support the establishment and/or expansion of industry support services. For example, the region requires a bioequivalence centre which is crucial for development and market approval of generic medicines. In order to promote innovation in the sector, there is need for establishment of incubation centres for proof of concept and prototype development. The COMESA Secretariat and the Member States should promote partnerships and collaborations between the various actors with the aim of scaling up the establishment of such centres. Other support services and industries that need to be promoted include specialised logistical services for medical products as well as packaging. Egypt and Ethiopia have gone a step further to establish specialised pharmaceutical parks which shared infrastructure services being provided. The other countries in the region should consider establishing similar parks if found to be viable in order to encourage investments in the sector.

Recommendation 9: Promote linkages and development of regional value chains

The study findings indicate weak linkages among value chain actors across the region. In order to leverage and optimise on the existing capacities to manufacture and supply selected medical products and attract additional investments there is need to strengthen linkages among the actors. This should be done through establishment of B2B exchange platforms both physical and virtual including hosting of regular medical products expo and exhibitions. Deliberate efforts should be made to promote regional value chains where competencies and complementarities exist across the region. For example, with market consolidation there is an opportunity for the region to produce selected APIs and other pharmaceutical inputs in one member state for uptake by manufacturers in the other countries. The same applies to the production of components for diagnostics and medical devices. There is the opportunity to promote backward and forward integration along the regional value chains. The region should leverage on the ongoing initiatives such as the operationalisation of the AcFTA to position the sector for investments that target not only the COMESA market but also for export.

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