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## Youth Employment in the Pharmaceutical Industry in Kenya

## Samantha Luseno and Sabina Obere

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YOUNG PROFESSIONALS (YPs) TRAINING PROGRAMME

# Youth Employment in the Pharmaceutical Industry in Kenya

Samantha Luseno and Sabina Obere

Kenya Institute for Public Policy Research and Analysis

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## Abstract

The challenge of creating jobs for the youth is at the core of the development agenda in Kenya. This agenda has been driven by the youth bulge that the country is experiencing which calls for adoption of targeted initiatives to actively involve the youth in the labour market. In line with this, the Government of Kenya made a commitment to create 1.3 million jobs for the youth annually during the Third Medium Term Plan 2018-2022 period by supporting value addition and development of industries with the potential to spur job creation and overall economic growth. The pharmaceutical industry in Kenya has been identified as one of such industries, with the potential to contribute to creation of both direct and indirect jobs. This study used value chain analysis as a guiding framework to assess how the industry can create more jobs and help in solving the youth employment challenge in the country. To do this, a mapping of the industry value chain was done and key constraints to the growth of the industry along the value chain identified. An analysis of the job creation potential of the industry was done using Labour to Value Added Ratios (LVAR), employment elasticities, and employment multipliers. Finally, a skills gap analysis was conducted by comparing the skills demanded by the industry and the skills that unemployed youth in Kenya have. From the value chain mapping, 88 per cent of local manufacturers engage in secondary manufacturing, 6 per cent in tertiary manufacturing with only 3 per cent engaging in research and development. Results from constraint analysis show that access to finance is a key cross cutting constraint across the value chain. This challenge prevents firms from upgrading to WHO compliance standards and accessing donor funding markets where WHO compliance is a prerequisite for participation in the tendering process. Challenges specific to wholesale and retail activities include highly fragmented markets and competition from unregistered firms. On job creation potential, results from elasticity estimations show that 10 per cent increase in Gross Value Added (GVA) by manufacturing firms would increase employment by 3.8 per cent and productivity growth by 62.0 per cent. This finding reinforces the argument that pharmaceutical manufacturing in Kenya is capital and technology intensive. On skills, the results show that jobs that require low skill levels can easily be filled by unemployed youth but those that require higher skills level cannot be easily filled by the unemployed youth

## **Abbreviations and Acronyms**

- AIDS Acquired Immune Deficiency Syndrome
- API Active Pharmaceutical Ingredient
- GDP Good Distribution Practices
- GMP Good Manufacturing Practice
- HIV Human Immunodeficiency Virus
- KEMSA Kenya Medical Supplies Agency
- KNBS Kenya National Bureau of Statistics
- MEDS Mission for Essential Drugs and Supplies
- PPB Pharmacy and Poisons Board
- R & D Research and Development
- UNIDO United Nations Industrial Development Organization
- USD United States Dollars
- WTO World Trade Organization
- NCE New Chemical Entity
- COC Certificates of Conformity

## **Definition of Terms**

**Manufacturing** is the process through which pharmaceutical companies synthesize finished drugs for wholesale distribution or consumption by the end user.

**Clinical trials** defined under section 2 of the Health Laws(Amendment) Act 2019, as any systematic study on pharmaceutical products in human subjects, whether in patients or other volunteers, to discover or verify the effects of, identifying any adverse reaction to investigational products, to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety.

**Processed and Unprocessed APIs** include dried glands and other organs for organotherapeutic uses, whether or not powdered; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, extracts of glands or other organs or of their secretions, for organo-therapeutic uses.

**Pharmaceutical preparations** include chemical contraceptive preparations, sterile surgical catgut, similar sterile suture materials, opacifying preparations for x-ray examinations, diagnostic reagents for administration to patients, first-aid boxes and kits, dental cements and other dental fillings, bone reconstruction cements, reagents for determining blood groups or blood factors, waste pharmaceuticals.

**Pharmaceutical wholesaling** involves purchase of finished pharmaceutical products in bulk from manufacturers and storing them in warehouses for distribution to dispensing agents such as pharmacies and hospitals.

**Pharmaceutical retailing** involves availing pharmaceutical products to the consumer at their point of need through retail outlets, pharmacies, chemists, shops, and health facilities.

**Good manufacturing practices** are aspects of quality assurance that ensure that medicinal products are consistently produced and controlled to the quality standards appropriate for their intended use as required by their product specification.

**Good distribution practices** are aspects of quality assurance that ensure that the quality of a pharmaceutical product is upheld through controlling activities that occur during the distribution process, such as procurement, purchasing, storage, distribution, transportation, repackaging, relabeling, documentation and record keeping.

**Donor funded markets** include those funded by donors such as the Global Fund to fight AIDS, Tuberculosis and Malaria; The US President's Emergency Plan for AIDS Relief (PEPFAR) which funds procurement of ARVs.

**Blood products** refers to human and animal blood; antisera and other blood fractions; and immunological products.

Bulk is the part of any drug that produces the intended effects.

Active Pharmaceutical Ingredient (API) refers to the chemical substance in the medicine that is biologically active. APIs are combined with excipients to produce final drugs.

Excipients are components of a drug that are not biologically active

## **Table of Contents**

Abs	stract	i		
Abbreviations and Acronymsii				
Def	Definition of Termsiii			
List	List of Figures			
List	t of Tables	vii		
1.	Introduction	1		
2.	Review of Regional and National Policies	5		
3.	Literature Review	10		
3.1	The Concept of Value Chain	10		
3.2	Theoretical Literature Review	10		
3.2.	1 Value chain theories	10		
3.2.	.2 Theory of constraints	11		
3.3	Empirical Literature Review	12		
3.3.	.1 Review of literature on pharmaceutical industry	12		
3.3.	.2 Review of literature on job creation potential	14		
3.4	Critique of literature	15		
4.	Methodology	15		
4.1	Introduction	15		
4.2	Conceptual Framework	15		
4.3	Mapping of the Value Chain	16		
4.4	Constraint Analysis	16		
4.5	Job Creation Potential	17		
4.5.	4.5.1 Job creation potential for direct employment17			
4.5.2 Job creation potential for indirect employment				
4.6	Skills Gaps Analysis	19		
4.7	Data Sources	20		
5.	Findings and Discussions	22		
5.1	Mapping of the Pharmaceutical Industry Value Chain in Kenya	22		
5.2	Explanation of Pharmaceutical Value Chain	23		
5.2.1 Manufacturing23				
5.2.	.2 Wholesaling	31		
5.2.3 Retailing				

5.3 Constraints to Growth of the Pharmaceutical Industry	33			
5.3.1 Constraints at manufacturing node				
5.3.2 Constraints at distribution node	39			
5.4 Job Creation Potential				
5.4.1 Direct employment				
5.4.2 Indirect employment				
5.5 Skills gap analysis in the pharmaceutical industry	45			
5.5.1 Pharmaceutical industry skills gap45				
6 Conclusion and Recommendations	52			
6.1 Conclusion	52			
6.2 Recommendations	52			

ferences55
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## List of Tables

Table 1: Regional and national policies guiding the pharmaceutical Industry 1	2
Table 2: Categorization of drugs under Schedule 1-4 based on the Kenya         National Drug Policy, 1994	0
Table 3: Regression results from elasticity approach    4	1
Table 4: Pharmaceutical industry skills gaps analysis	3
Table 5: Occupational skills gap for pharmaceutical manufacturing4	5

## List of Figures

Figure 1: Five steps of eliminating constraints in a value chain
Figure 2: Conceptual framework
Figure 3: Imports and exports of processed and unprocessed APIs in Kenva
between 2007 and 2018 in millions of Ksh
Figure 4: Importer and average value of exports of processed and unprocessed
APIs between 2007 and 2018
Figure 5: Tree map of exporter and average value of imports of processed and
unprocessed APIs between 2007 and 2018
Figure 6: Imports and exports of blood products in Kenva between 2007 and 2018
in billions of Ksh
Figure 7: Importer and average value of exports for blood products between 2007
and 2018
Figure 8: Tree map of exporter and average value of imports of blood products
between 2007 and 2018
Figure 9: Imports and exports of medicaments in measured doses in Kenva
between 2007 and 2018 in billions of Ksh
Figure 10: Importer and average value of exports for medicaments in measured
doses between 2007 and 201825
Figure 11: Tree map of exporter and average value of imports of medicaments in
measured doses between 2007 and 2018
Figure 12: Imports and exports of pharmaceutical products in Kenva between
2007 and 2018 in '000 US dollars
Figure 13: Aggregate value of imports and exports by product between 2007 and
2018
Figure 14: Access to finance as an obstacle for firms in the pharmaceutical value
chain in Kenya
Figure 15: Access to finance as an obstacle for firms in pharmaceutical
manufacturing by firm size
Figure 16: Skills shortage as an obstacle for firms in the pharmaceutical value
chain in Kenya
Figure 17: Skills shortage as an obstacle for pharmaceutical manufacturing by firm
size
Figure 18: Competition from unregistered firms
Figure 19: Labour to value added ratios for various manufacturing sub-sectors 38
Figure 20: Gender inclusion within pharmaceutical manufacturing
Figure 21: Employment based on projections
Figure 22: Indirect employment within the pharmaceutical industry40
Figure 23: Occupational profile for the pharmaceutical manufacturing
Figure 24: Mapping of occupations in pharmaceutical manufacturing organized in
order of hierarchy
Figure 25:Occupational profile for wholesale of pharmaceutical products46
Figure 26: Occupational profile for retail pharmaceutical products

## 1. Introduction

The pharmaceutical industry in Sub-Saharan Africa industry has been identified as an industry with the potential to contribute immensely to job creation. The industry comprises establishments, both private and public that are involved in the process of discovering, developing, manufacturing, distribution and marketing of drug (Murray, 2016). A thriving pharmaceutical industry has a direct and significant impact on job creation as it provides both direct and indirect jobs for skilled and semi-skilled workers. The direct jobs are in research and development and pharmaceutical manufacturing, while indirect jobs are in pharmaceutical distribution (wholesalers and retailers). The industry also creates other jobs through a spill-over effect in other manufacturing industries and services that support the pharmaceutical industry, for instance the logistics and transport industry (Ahmed et al., 2018; Lartey et al, 2018).

Job creation potential for the pharmaceutical industry is directly linked to its growth in market value. Therefore, given the impressive growth rate in market value that has been recorded in the recent past and the projected growth trajectories, the overall job creation for the industry is expected to increase (UNIDO, 2019). Specifically, the industry's market value grew at a Compound Annual Growth Rate (CAGR) of 16 per cent from US\$ 4.7 billion in 2003 to US\$ 20.8 billion in 2013 and value of the pharmaceutical industry is projected to further increase twice-fold to US\$ 40 billion by 2020 (World Bank, 2019; UNIDO, 2019).

This link between pharmaceutical industry growth and employment creation has led to a renewed emphasis at regional and national level to support growth of the industry through development of industry plans and targeted policies. The African Union Pharmaceutical Manufacturing Plan for Africa, and the 2<sup>nd</sup> East African Community (EAC) Regional Pharmaceutical Plan of Action 2017-2027 focus on enhancing competitiveness of the industry by reducing dependence on exports; promoting procurement of locally manufactured pharmaceutical products; increasing the pharmaceutical product portfolio; and increasing the number of companies producing advanced pharmaceutical formulations.

At national level, the Government of Kenya (GOK) in support of these regional strategies has prioritized development of the industry due to the dual role it plays of creating employment while supporting two pillars of the Big Four Agenda. The industry is instrumental in increasing the contribution of manufacturing to Gross Domestic Product (GDP) to 15 per cent by 2022 as it is one of the industries driving growth within the manufacture of non-food products. From the Economic Survey 2020, manufacture of pharmaceuticals steered growth within manufacture of non-food products by 6 per cent on account of increased production of capsules,

syrups, and tablets by 9.3, 6.9 and 4.4 per cent, respectively. The industry is also central in attainment of Universal Health Coverage (UHC) through enhancing access to safe, effective, quality, and affordable essential medicines and vaccines for all.

Currently, Kenya has one of the fastest-growing pharmaceutical industries in Sub-Saharan Africa with a projected CAGR of between 7.6 per cent and 12 per cent from 2018 until 2023. The country also has the largest pharmaceutical industry within the East African Community with a market share of Ksh 7.5 billion (World Bank, 2019; East African Community, 2018). Growth in Kenya's pharmaceutical industry has been driven by increase in both domestic demand and regional demand. The value of exports increased at a CAGR of 5.3 per cent from Ksh 6.97 billion in 2006 to Ksh 13.01 billion in 2018 (ITC, 2019) The value of domestic demand has grown at a CAGR of 10.6 per cent from Ksh 29.4 billion in 2007 to Ksh 80.4 billion in 2018 (ITC, 2019). The key reasons for this growth in domestic demand for medicines used in treatment of communicable and non-communicable diseases on account of the rapidly expanding Kenyan population (East African Community, 2018; World Bank, 2019).

With the growth of the pharmaceutical industry in Kenya, there has been increase in direct and indirect job creation within the industry. Direct jobs (those in manufacturing) have increased by 28 per cent from 3,389 in 2007 to 4,322 while indirect jobs (those in wholesaling and retailing) have increased by 38 per cent from 5,761 in 2007 to 7,944 in 2018 (Kenya National Bureau of Statistics, 2019).

The relationship between the pharmaceutical industry and job creation point to the pivotal role it plays in achieving the Sustainable Development Goal (SDG) 8, which aims to create full and productive employment and decent work for all, and sustainable economic development. In particular, focus on improving growth within the industry has the potential to address the challenge of youth employment, which is at the centre of the Kenya Government agenda. This agenda is largely driven by the realization that the growing Kenyan population is accompanied by a demographic transition characterized by a youth bulge. According to the 2019 Kenya Population and Housing Census, the youth (those between 15-34) represent 36 per cent of the total population. With these demographics, it is evident that the youth bulge phenomenon in Kenya is likely to continue. Therefore, it is imperative to tap into the demographic dividend that the youth bulge phenomenon presents by ensuring that the youth participate in the labour market through gainful employment. To effectively do this, the Government has focused on supporting growth and value addition in the pharmaceutical industry through targeted policies and initiatives as it is an industry with the potential to contribute immensely to job creation. For instance, the Kenya National Pharmaceutical Policy 2010, which is the guiding framework in the industry, focuses on supporting local manufacturing of essential drugs for both domestic consumption and exports. Similarly, the Sessional Paper No. 9 of 2012 on the National Industrialization Policy Framework for Kenya 2012-2030 recognizes the pharmaceutical industry as a frontier industry with the potential to drive industrial growth through its ability to meet domestic and regional demand for pharmaceutical products, and its ability to create jobs. Therefore, the policy focuses on promoting growth in the industry by encouraging the use of local raw material for the manufacture of pharmaceutical products.

Despite these targeted policy initiatives by the Government, the pharmaceutical industry in Kenya is not performing optimally as per the envisioned targets. First, the industry is heavily reliant on imports for both finished pharmaceutical products and raw materials. High importation of finished pharmaceuticals is in part caused by local manufacturers not expanding their product portfolio and their focus on production of simple formulation medicines such as antibacterials, analgesics, vitamins, coughs and cold preparations while expensive innovative medicines such as anticancer drugs, immune-suppresive drugs, or blood components are exclusively imported (East African Community, 2018; Hasan, Wanyanga, Reinhardt, West and Vohrer, 2010). Based on this, 70 per cent of the domestic market comprises of imported pharmaceutical products.

High importation of raw materials is due to the country importing 90 per cent of Active Pharmaceutical Ingredients (APIs), which are the main input in pharmaceutical productions. Further, inputs such as packaging products and excipients, which can be sourced locally are also imported (Hasan et al., 2010). In monetary terms, the growth in value of imports has been at a CAGR of 8.7 per cent from Ksh 22.22 billion in 2007 to Ksh 55.84 billion in 2018 (ITC, 2019).

Second, Kenya's exports to its key destinations within the East African Community have been on a decline since 2014. Exports to Rwanda decreased by 43 per cent from Ksh 1.36 billion in 2014 to Ksh 0.77 billion in 2018. In Tanzania, the value of exports reduced by 32 per cent from Ksh 4.08 billion to Ksh 2.78 billion while in Uganda, exports reduced by 21 per cent from Ksh 2.702 billion to Ksh 2.125 billion from 2014 to 2018. The decline in value of exports to these countries is attributed to the efforts that Tanzania, Rwanda and Uganda are making to reduce their dependency on pharmaceutical imports by promoting their local pharmaceutical manufacturing industries. The decline in market for Kenya's pharmaceutical

exports within the East African Community has resulted into a marginal growth in export at a CAGR of 5.3 per cent from Ksh 6.97 billion in 2007 to Ksh 13.01 billion in 2018.

Although total employment within the industry has grown at a CAGR of 2.7 per cent from 9,150 in 2007 to 12,266 in 2018, the contribution of the pharmaceutical industry to total wage employment in Kenya has decreased from 0.48 per cent to 0.44 per cent. There has also been a decline in the contribution of direct employment to total employment within the pharmaceutical industry by 2 percentage points from 37 per cent in 2007 to 35 per cent in 2018. The contribution of indirect employment to total employment within the industry increased by 2 percentage points from 63 per cent to 65 per cent during a similar period (ITC, 2019)

Further, the employment creation seen within the pharmaceutical industry in Kenya is significantly lower in comparison with countries that have well established pharmaceutical industries. Bangladesh, for instance, employs about 1 million people in the pharmaceutical industry with over 70 per cent of those employed working in the manufacture of pharmaceuticals (National Skills Development Council Secretariat, 2017). Further, Bangladesh has consistently recorded an increase in direct employment as a share of total employment within the pharmaceutical industry, with increase in overall growth rate in the pharmaceutical industry. Pakistan directly employs about 450,000 people in the manufacture of drugs with an additional 4 million employed indirectly in other activities such as pharmaceutical distribution, wholesale and retail (Ahmed et al., 2018).

As such, this study uses a value chain methodological approach to evaluate the key constraints facing the pharmaceutical industry and the potential of the industry to provide employment especially for the unemployed youth. Previous studies in the pharmaceutical industry have focused on the role of the industry in provision of effective, efficient, affordable, and high-quality essential medicines for Universal Health Coverage. There is no study in Kenya, to the best of our knowledge, that has been conducted on the job creation potential in the industry. It is this gap in the body of literature that our study intends to fill.

The overall aim of this study is to evaluate the potential of the pharmaceutical industry to create jobs and identify the required and available skills-set among the unemployed youth in Kenya. Specifically, the study fulfils the following objectives: First, map the pharmaceutical industry value chain; second, identify the key constraints within the value chain; third, assess the current employment creation potential along the pharmaceutical industry value chain and lastly, analyze the labour skills requirements of the pharmaceutical industry and compare it with the existing labour skills of the unemployed youth.

The rest of this paper is organized as follows: section 2 reviews the policy and legislative framework that governs the operations in the pharmaceutical industry; literature review is presented in section 2; section 4 presents the methodology; study findings and discussions are presented in section 5; while section 6 concludes and makes policy recommendations.

## 2. Review of Regional and National Policies

Cognizant of the critical role that the pharmaceutical industry plays in the economy, the focus of stakeholders within the industry at regional and national level has been to strengthen it by addressing pertinent issues that it faces. To this end, industry plans and policies have been developed both at regional and national level. A review of some of these policies as presented in Table 1 shows what has been done in terms of implementing these policies and the gaps that need to be addressed for effective operation of the industry as a whole.

# Table 1: Regional and national policies guiding the pharmaceutical industry

Policy	Objectives	Focus on the pharmaceutical industry	What has been done	Gaps
		<b>Regional Poli</b>	cies	
Pharmaceutical Manufacturing Plan for Africa Business Plan (PMPA-BP)	To enhance the pharmaceutical manufacturing in Sub- Saharan Africa for supply of high-quality affordable medicines, improve public health and promote economic growth	Identified key constraints facing the pharmaceutical industry in Africa and possible ways of addressing them	Kenya developed a Good Manufacturing Roadmap in 2014 in line with the proposal of the plan The East African Community developed a regional pharmaceutical Manufacturing Plan of Action in line with the proposal of the plan	Regional harmonization of regulations to enhance market access for pharmaceutical products has not been done within the East African Community The proposal of having partnerships between those in the industry and training institutions to ensure that the curriculum reflects the needs of the industry has not been implemented for the Kenyan pharmaceutical industry

East Africa Community RegionalSupport local manufacturing within the pharmaceutical industry to meet local and regional demand, create jobs and increase foreign exchange through reduced importsEncourage local manufacturers to attain international recognized quality standards by setting up a regional GMP roadmapReversing the dependency of pharmaceuticals products from more than 70% to less than 50%Introducing and implementing incentive packages and appropriate financing schemes for local pharmaceutical products from more than 70% to less than 50%Enhancing expansion of EAC manufacturing firms product portfolio to cover more than 90% of disease conditionsDeveloping and implementing a regional strategy for promoting appropriate skills mix for the pharmaceutical manufacturersBensuring that at least 50% of EAC medicines procurement are sourced from EAC manufacturersDeveloping and implementing a regional strategy for promoting appropriate skills mix for the pharmaceutical manufacturing industry		A regional GMP roadmap has not been set up to encourage manufacturers to attain international recognized quality standards Regional harmonization of regulations to enhance market access within member countries
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Domestic Policies and legislations				
Kenya National Drug Policy, 1994	Ensuring that the available resources are optimized for provision of affordable, high quality and efficient medicines for treatment of diseases	Ensuring that everyone can access safe and effective drugs Expand the supply chain by including government, private and non-government organizations Encourage local manufacture of drugs for both domestic market and exports	Establishment of Kenya Medical Supplies Agency (KEMSA) through Legal Notice No. 17 Improving the capacity of Pharmacies and Poisons Board (PPB) to perform its duties through continuous training of its staff on industry regulations Enhancing the National Quality Control Laboratory capacity to attain WHO prequalification status	The section on supporting local manufacture of drugs for domestic and export market was not fully implemented due to lack of an enabling and institutional framework The Directorate of Pharmaceutical Services proposed to oversee day to day functions of public sector pharmaceutical services was not implemented

Kenya National Pharmaceutical Policy 2010	Creating an enabling environment to encourage investment in local production of high-quality essential medicines and compliance with GMP practices Encourage technological transfer and international accreditation of local manufacturers to enhance their competitiveness Harmonization of all relevant statutes to address constraints to local manufacturing Developing incentives to encourage investment in local pharmaceutical production	Strengthening the pharmaceutical sector regulations Establishing a Directorate of Pharmaceutical Services (DPS) as the structure of governance within the industry separate from the Directorate of Medical Services	Incentives such as KEMSA giving a 15% preference for local firms involved in manufacture of pharmaceuticals Exemption of taxes and duties on some raw materials such as excipients, APIs and some packaging materials	Harmonization of all relevant statutes to address constraints to local manufacturing has not been implemented
Sessional Paper No. 9 of 2012 on National Industrialization Policy framework for Kenya 2012- 2030	Drive growth in the industrial sector to an annual growth rate of 15% and maintain this growth rate in subsequent periods Support development of the pharmaceutical industry due to the potential it has to spur growth	Promoting procurement of locally manufactured pharmaceutical products Encouraging the use of local materials for manufacture of pharmaceutical products Ensuring the training of more specialized personnel to cater for research and development needs, industrial pharmacy, biotechnology as well as quality control assurance		The cooperation between the industry and training institutions and the development of technical, production and managerial skills to address skills mismatch has not been done Industrial Development Fund (IDF) proposed to facilitate access to affordable long term finance for manufacturing entities has not been institutionalized National Industrial Development Commission proposed to provide a framework for a consultative approach to industrial development has not been institutionalized

## 3. Literature Review

## 3.1 The Concept of Value Chain

A value chain is an array of value adding activities undertaken by a firm or firms to bring a product or a service from its conception to use by the final consumer (Kaplinsky and Morris, 2001). This definition of a value chain is interpreted in two-folds. First, in a narrow sense to encompass the range of activities performed within a firm to produce an output. These activities might include product conception and design stage; acquisition of input; production; marketing and distribution; and other related after-sale services aimed at ensuring that the consumer is satisfied with the product or service. Second, in a broad sense by looking at the complex range of activities implemented by various actors (primary producers, processors, traders, service providers), to bring a raw material through a chain to the sale of the final product. The broad definition looks at backward and forward linkages across firms until the level when the final product or service is delivered to the consumer (UK Department for International Development, 2008). As such, it is imperative to analyze the flow of information, coordination, power relation and the rules that govern the interactions between the different actors in the broad definition of a value chain.

Value chain analysis entails breaking a value chain into its basic parts and activities to understand its structure; key players at each stage; functions and relationships between these key players; flow of information among players; and what governs their cooperation and competition (Page, 2019).

## 3.2 Theoretical Literature Review

#### 3.2.1 Value chain theories

There are several theories that have been advanced to explain the concept of value chain. These theories have informed major research streams in value chain analysis literature. The first is the filiere approach, which has its origin in France and basically means thread. The approach provides an empirical perspective for mapping the agricultural production system while identifying actors and the flow of activities between the actors. Although the rationale of filiere is similar to the broad concept of value chain, it directly ties value chains with physical transformation. To this end, it focuses on physical and quantitative technical relationships which are summarized in flow charts of commodities and mapping of transformation relationship (DfID, 2008; Kaplinsky and Morris, 2001).

The second approach is known as Porter's framework. From this approach, value chains provide a tool for firms to determine their source of competitive

advantage. More specifically, value addition from this approach is informed by firms interrogating ways in which they can produce quality goods and services at a lower cost in comparison with their competitors, or ways in which they can produce differentiated products which customers are willing to pay more for. This approach differs from the filiere approach since it delinks value addition with physical transformation and instead focuses on the aspect of competitive advantage in identification of value adding activities in firms (Porter, 1985).

The global approach applies the concept of value chains cognizant of the rapid globalization which has taken place over the years. To this end, it recognizes that in most cases, inputs and semi-finished goods and services are imported, value is added locally, then the product is exported for further processing and consumption by the final user (Farole et al., 2018). This global approach of value chain analysis was further used by Kaplinsky and Morris (2001) to explain income disparities between, within and across countries as they participate in a global value chain.

#### 3.2.2 Theory of Constraints

The Theory of Constraints (TOC) was proposed by Eliyahu M. Goldratt as a scientific approach of analyzing constraints. The basic tenet of TOC is that every system has a single constraint which is often the weakest link in the chain, and that the overall performance of the system can only be improved if the limiting factor is addressed. Therefore, the theory takes a scientific approach to organizations' improvement by identifying this constraint then focusing on its consistent improvement until it is no longer considered as a limiting factor (Goldratt et al., 1984).

Improvement of the constraint is done using a five focusing steps approach presented in Figure 1, which involves identifying the constraint and its impact on the goal; exploiting the key constraint identified; subordinating everything else to the decision of exploiting the constraint; elevating the system's constraint by focusing on the next limiting factor after the first constraint has been solved; and repeating the process until all constraints identified within the system are addressed (Goldratt, 1990).



Figure 1: Five steps of eliminating constraints in a value chain

Source: Authors' construct based on Goldratt (1990)

TOC has two major shortcomings which are directly linked to its assumptions. First, the theory assumes that every process has a single constraint that can be addressed independently. However, most systems often have more than one limiting factor, which are interrelated and need to be addressed simultaneously to improve the overall performance of the system. Also, there are instances where ranking constraints in terms of the most severe to the least severe is often not feasible. The above-mentioned assumption presents major shortcomings of the theory especially when it comes to its applicability in systems that have more than one limiting factor (Goldratt, 1984). Despite these limitations, the theory has been successfully used to enhance productivity in manufacturing and its use has gradually expanded to include areas such as production, supply chain, distribution, and retail (Ikerizi et al., 2018).

This study will apply the theory of constraints to the pharmaceutical industry value chain and use the five steps focusing approach to identify and address constraints for every activity that deters the industry from achieving its goal of enhancing its competitiveness domestically and regionally, while creating jobs.

### 3.3 Empirical Literature Review

#### 3.3.1 Review of literature on pharmaceutical industry

A vast body of literature exists on studies conducted on the pharmaceutical industry. These studies, however, vary in their methodology and survey design with each study laying emphasis on a different aspect of the industry.

To identify problems facing the pharmaceutical industry and ways of ensuring its long-term viability, Baines (2010) conducted interviews with heads of pharmaceutical companies and other key industry stakeholders in the United States amidst a slowdown in economic activity. The results identified reduction in discovery, approval and marketing of New Chemical Entities (NCE), competition from generic drugs, pressure from regulatory authorities, together with slow growth in the US market as the key bottlenecks inhibiting the expansion of the industry. Although this study was done in the US, a developed economy, the results are consistent with those from studies done for pharmaceutical industries in developing economies within Sub-Saharan Africa. Other additional constraints that the industry faces which are unique to developing countries as identified by other studies include: skills shortage; influx of the market with counterfeit drugs; poor Good Manufacturing Practice (GMP) compliance; weak regulatory framework; poor technologies; limited access to markets; inadequate data on the market; and lack of partnerships between the players in the industry (Lartey et al., 2018; World Bank, 2019).

By employing Bootstrapping and Normal theory methods, a quantitative analysis of the pharmaceutical industry in Pakistan by Ahmed et al. (2018) indicate that the industry plays a pivotal role in creating jobs within the economy. The results showed that there exists a direct and significant relationship between the industry and creation of direct, indirect and spillover jobs. Direct jobs as defined in the study are those in manufacturing of pharmaceuticals, indirect jobs are those in other activities within the industry, for instance wholesale activities and retail activities. Spillover jobs, on the other hand, are those in other industries that support the pharmaceutical industry, for instance transport and logistics. Most specifically, the industry provides direct employment to 450,000 people and indirect employment to over 4 million people. A similar trend is witnessed for the pharmaceutical industry in Bangladesh, which provides about 1 million jobs of which 70 per cent are in manufacturing while the other 30 per cent are indirect jobs and in the US where the industry directly employs more than 810,000 people and an additional 2.59 million indirectly (National Skills Development Council Secretariat, 2017; Muratoglu, 2017).

A survey done by the World Bank in 2019 on the pharmaceutical industry in Kenya directly links its job creation with the ability of firms within the industry to enhance their market access by meeting international quality standards. These standards range from Good Manufacturing Practice for manufacturing and Good Distribution Practices for wholesale and retail activities. From the survey, the 8 manufacturing firms reported that they employed 3,600 people in direct jobs, with about 67 per cent in low-skilled jobs and the other 33 per cent in semi-skilled jobs and high skilled jobs. The report further projected creation of an additional 1,200 direct jobs by 2022 should import dependency remain constant and demand for pharmaceutical products grow by 7.5 per cent annually. As the industry expands and moves towards local production and self-sufficiency, jobs will be created in areas such as producers of packaging material for pharmaceuticals such as glass bottles and cartons, which are increasingly required but are imported. Other jobs that might be created include: quality assurance officers; site supervisors, sales and marketers, and quality controllers (East African Community, 2018; World Bank, 2019). The industry will also require technicians to repair and maintain machinery used in pharmaceutical manufacturing and machine operators with electronics background, chemical mixing operators, dispensing operators and coating operators (National Skills Development Council Secretariat, 2017).

An analysis of the pharmaceutical industry in Bangladesh by the National Skills Development Secretariat (2017) showed that skilled manpower is in high demand within the industry, and that the industry faces a relatively high turnover rate in high skilled individuals. Further, the study pointed out that the curriculum of vocational training centres and academic institutes are not updated with the current needs of the industry. The results of this analysis mirror the pharmaceutical industry in Africa as outlined in the Pharmaceutical Manufacturing Plan for Africa- Business Plan. From the plan, training institutions provide graduates with a solid foundation in scientific theory, which is needed in the industry. However, the students are not sufficiently taught the industrial applicability of these scientific theories. As a result, graduates must undergo additional training that is industry-oriented to make them better equipped to perform their jobs. These findings are consistent with results from a survey done by the World Bank in 2019 on the pharmaceutical industry in Kenya. From this survey, firms that hired locally for positions such as industrial pharmacists, chemists, microbiologists, site supervisors and engineers reported that recent graduates were inadequately prepared to work in the industry. As a result, they had to divert significant resources in terms of time and money from the production process to train these graduates on the industry requirements.

Also, an examination of the development of pharmacy education in Kenya since independence by Ogaji et al. (2016) shows that there has been a shift in focus in the

Kenyan pharmaceutical curriculum into clinical pharmacy, which is more patientoriented. In line with this, Kenyan universities have established partnerships with other institutions of higher learning to support training on Clinical Pharmacy and Pharmacotherapeutics. For instance, the Indiana University School of Medicine (IUSM) has been working with Moi University School of Medicine and the University of Nairobi to offer such trainings for pharmacists. These initiatives have resulted into a pool of graduates who have practical skills in clinical pharmacy and pharmaceutical care but very little practical skills and exposure to industrial pharmacy (World Bank, 2019; Hasan et al., 2010; Ogaji et al., 2016). This is worrisome considering that the pharmaceutical industry in Kenya is in need of those with a training on industrial pharmacy.

#### 3.3.2 Review of literature on job creation potential

It is through understanding the employment intensity of a sector that its job creation potential can be estimated. Therefore, employment intensity indicators provide a starting point in measuring job creation potential. To this end, literature on job creation potential outlines four main measures of employment intensity: labour-capital ratio, labour-value added ratio, employment multipliers, and employment elasticity. However, the choice of which measure of employment intensity to be used in computing job creation potential in a specific context is guided by data availability, computational capacity, and the purpose for which the measure of employment intensity is needed.

Labour-capital ratio shows how labour absorbing an activity is for each unit of capital invested while labour-value added ratio measures how labour absorbing an activity is for each unit of value added. These measures of employment intensity have been used in South Africa using different data sets. Bhorat et al. (2019), for instance, use GDP data for South Africa and with Quarterly Labour Force Survey (QLFS) to compare labour to value added ratios for different sectors in South Africa. Results from this analysis show that the lowest ratios are found in: mining and quarrying; electricity, gas and water supply; transport storage and communication; and financial services. The highest ratios are found in community, social and personal services and construction. A similar approach is utilized by Tregenna (2015) in South Africa using data from South African Standardized Industry Database (SASID), the October Household Survey (OHS), and the Labour Force Survey (LFS).

Tregenna (2015) points out that the shortcoming of both labour-capital and labour value-added ratio is that they only measure direct employment intensity within a sector. Further, Bhorat et al. (2019) stresses on the need to use these ratios together with other measures of employment intensity especially when it comes to analyzing job creation potential since their power in predicting future employment trend is limited in scope.

Employment multipliers are a broader measure of employment intensity that give both direct and indirect employment intensity of a sector (Tregenna, 2015). In a broad sense, employment multipliers show how a change in final output of a sector results in a change in jobs in the wider economy. Studies that have used employment multipliers as a measure of employment intensity have varied in approach. Van Dijk (2017) estimates the local multiplier effect for Metropolitan Statistical Areas (MSA) in the US using census data. Results from this analysis indicate that each additional job in the tradable sector creates between 1.6 and 1.7 new jobs in the non-tradable sector. A bigger multiplier of between 2.0 to 2.3 is obtained on separating the tradable sector into high and low wage workers.

Tregenna (2008) estimates total employment multipliers in South Africa using SASID data. The results from this analysis show that total employment multipliers for services is higher than that for manufacturing. Specifically, a R1 million increase in final demand for services would create 5.46 jobs compared with 4 jobs associated with a R1 million increase in final demand for manufacturing. When it comes to indirect jobs, manufacturing generates more indirect jobs in services with a R1 million increase in final demand for manufacturing resulting into 1.37 jobs in services whereas a similar increase in final demand for services is associated with only 0.22 jobs within manufacturing.

#### 3.4 Critique of literature

From the theoretical literature review on value chains, the global approach best explains the pharmaceutical industry value chain as it considers the interaction of firms within the industry and other firms globally through imports and exports. The pharmaceutical industry in Kenya imports both finished medicines from countries such as China, India and Malaysia in bulk for re-exports to other countries within the East African Community (Tanzania, Uganda, and Rwanda). The major imports include Active Pharmaceutical Ingredients (APIs) and excipients, primary packaging materials, machinery, and equipment. These inputs constitute raw materials, which are used for the manufacture of medicines for domestic consumption and export. The applicability of filiere approach for the industry in Kenya is limited as this approach is directly tied to agricultural setting and links value addition to physical transformation (Kaplinsky and Morris, 2001; DfID, 2008).

From empirical literature review, it is evident that most studies done on job creation potential using measures of employment intensity have focused on South Africa and with emphasis on manufacturing sector and the service sector. However, none of the studies applied these measures of employment elasticity to the pharmaceutical industry. It is this gap in literature that this study intends to fill.

## 4. Methodology

#### 4.1 Introduction

The study used a mix of analytical approaches with the main framework being within the value chain. The following activities are undertaken: mapping the pharmaceutical industry value chain; constraint analysis; assessment of labour supply versus labour demand; and the assessment of job creation potential using labour to value added ratios, employment elasticities, and employment multipliers.

#### 4.2 Conceptual Framework

The study envisions that enhancing the competitiveness of the pharmaceutical industry to meet domestic and regional demand would essentially create more, better and inclusive jobs for the youth in Kenya. It assumes that addressing constraints hindering the growth of the industry will enhance the capacity of the pharmaceutical industry to absorb employees. The jobs created will vary from skilled to unskilled and hence an assessment of labour supply versus labour demand is undertaken.



#### **Figure 2: Conceptual framework**

Source: Authors' construct

## 4.3 Mapping of the Value Chain

A generic value chain giving an understanding of the flow of activities as pharmaceutical products move from the raw material stage to use by the final consumer was mapped. The map was then adjusted to fit the Kenyan context, clearly articulating the following: firm characteristics such as at each node; interactions with the non-domestic market players through imports and exports (global value chain); evolution of employment at each node; and highlighting governance structures by node. The section will be based on an extensive literature review of the industry.

## 4.4 Constraint Analysis

Data from the World Bank Enterprise Survey 2018 informed the constraint analysis. The data set collects firm-level country specific data following a standard methodology on firms' experiences and enterprises' perception of the environment in which they operate. Our unit of analysis was private firms within the pharmaceutical industry. These firms were involved in manufacture of pharmaceutical, wholesaling and retail activities.

Our identification of constraints was guided by the theory of constraints in addition to broadly categorizing the constraints into those related to the business environment and those on investment climate. The survey further allows firms to rank the severity of constrains identified into five categories: no obstacle, minor obstacle, moderate obstacle, major obstacle, and very severe obstacle. For each constraint identified, we analyzed its level of severity across the activities of the value chain to establish in which activity the constraint is most prominent.

The results from World Bank Enterprise Survey 2018 constraint analysis was complemented with findings from extensive literature review of relevant reports, studies, policies, strategies and available profiles of the pharmaceutical industry in Kenya. This was done to obtain a comprehensive constraint analysis of the pharmaceutical industry in Kenya.

## 4.5 Job Creation Potential

## 4.5.1 Job creation potential for direct employment

## Labour-capital and labour-value added ratios

Labour-capital and labour value added ratios show how intensively labour is used within the production process. We developed a vector of employment and sector GDP for each sector considered for comparison ( $P_{(n\times 1)}$  and  $X_{(n\times 1)}$ ).

We then transformed the vectors into a diagonal matrix of the form  $n \times n$  denoted by DIAG(P) and DIAG(X) made up of elements of P( $n \times 1$ ) and X( $n \times 1$ ). The labour value ratio was calculated as follows:

$$N=DIAG(P) (DIAG(X))^{-1}$$
(1)

Where:

 $P(n \times 1)$  represents a vector of employment per industry

 $X(n \times 1)$  represents a vector of GDP for each industry considered

The ratios were computed using employment and GDP data obtained from the Census of Industrial Production, 2010

#### Employment elasticities: Regression approach

Employment elasticity shows how a given sector's employment can grow in the future given a particular GDP growth trajectory. Employment elasticities has been used by various researchers to model employment growth potential (Fox et al., 2013; Ali, Ghazi and Msadfa, 2017). Like in these studies, the employment elasticity will serve the purpose of measuring the responsiveness of employment to growth of output for the pharmaceutical industry. The relationship is expressed as follows:

$$\delta \ln(E_t) = \alpha + \beta \ln(VA_t) + \varepsilon_t \tag{2}$$

Where:

 $E_t$  is the sectoral employment level at period t

 $\alpha$  is the constant term

 $\beta$  is the employment elasticity to be estimated

VA, the sectoral value added by the pharmaceutical industry at period t

Projections are made taking cognizance of the arithmetic identity that links employment elasticities to labour productivity. The relationship is expressed as follows:

$$VA_{t}=E_{t}P_{t}$$
(3)

Where

 $P_t$  is the labour productivity/ output per worker.

For small changes in output the following holds:

$$\Delta VA_t = \Delta E_t + \Delta P_t \tag{4}$$

If we divide across by  $\Delta VA_t$ , the following is derived:

 $\beta = (\Delta E_t) / (\Delta V A_t) = 1 - (\Delta P_t) / (\Delta V A_t)$ (5)

(Fox et al., 2013; Kapsos, 2005)

To undertake projections using the elasticity estimates, the following general assumptions are made: First that the structure of the population and representation of the youth in Kenya remains the same, and that the industry growth rate stood between 7.66 per cent and 12 per cent between 2018 and 2023 (World Bank, 2019).

The key limitations of this approach is based on the nature of the equation used to estimate employment elasticities and the number of estimations in the panel data. Due to lack of control variables, the estimations are likely to suffer from omitted variable bias.

#### 4.5.2 Job creation potential for indirect employment

#### Employment multipliers: Regression approach

The study adopts the classification of the pharmaceutical manufacturing node as the direct activity within the mapping of the value chain while considering all other activities in the value chain as indirect activities in the chain (Ahmed, Vveinhardt, and Streimikiene, 2018). It further categorizes pharmaceutical manufacturing as a tradable sub-sector and all other sub-sectors as non-tradable as per the definition proposed by Mano and Castillano (2015). In light of this, it adopts the use of local multipliers, which measure the impact of tradable employment (pharmaceutical manufacturing) on non-tradable sectors (wholesale and retail). Employment multipliers will be computed using the regression approach.

$$\Delta Employment_{t}^{\text{Direct Activity}} = constant + \beta \Delta Employment_{t}^{(\text{Indirect/induced Activity})} + \varepsilon$$
(6)

Where:

Direct activity represents pharmaceutical manufacturing

Indirect activity represents wholesale and retail

If  $\beta$  is positive, then an increase in employment in pharmaceutical manufacturing would lead to increased employment in indirect activities (wholesale and retail) within the value chain.

#### 4.6 Skills Gaps Analysis

Skills is the ability to effectively carry out the tasks of a given job. A skills gap is the difference between the skills employers need for a job and the skills that prospective employees in the labour market possess (ACT, 2011). A skills gap exists where there are open positions, but employers cannot find individuals with the required skills from the labour market to fill these positions. Skills gap analysis is increasingly becoming important for policy makers with the growing body of literature which points out that there exists a discrepancy between what the industry requires and what is taught in institutions of higher learning (World Bank, 2019; Hasan et al., 2010; UNIDO, 2019). Since our study involves creating jobs within the pharmaceutical industry, it is imperative to identify the skills requirements of the industry and compare it with the existing skills of unemployed youth to give an indication of skills gap and possible ways of addressing the identified gaps to enhance youth employment within the industry.

We intend to measure skills gap in two ways: an industry skills gap, and an occupational skills gap. For the industry skills gap, we will obtain the skills supply of unemployed youth from Kenya Integrated Household Budget Survey (KIHBS) data separated by education levels as follows:

$$S = [s_1, s_2, \dots, s_j]$$
 (7)

Then we will obtain the number of workers required disintegrated by education level for the industry by adding the workers needed in each skill level for all occupations in the industry specified as:

$$D=[d1, d2, ...dj,]$$
 (8)

We will then obtain the industry skills gap by subtracting skills requirement presented by D from skill supply represented by S as follows:

$$S-D=[(s_1-d_1),(s_2-d_2),...(s_j-d_j)]$$
(9)

The industry skills gap obtained represents the extent to which the skills required in the industry, measured using levels of education, exist within the unemployed youth.

The limitation of this measurement of skills gap is that it only indicates whether the skills needed in the industry exist among the unemployed without considering that not all the unemployed youth will get jobs in this industry. Therefore, we intend to complement the skills gap with skills availability ratio.

Skills ratio measures the skills that exist in unemployed youth against the skills that are required by the industry for each education level. A high skills ratio shows that the skills required in the industry will be accessed in the specific industry. A low ratio shows that the skills may be available within the unemployed youth, but they will not be available for the specific industry.

The other measure of skills gap will be occupational skills gap, which is calculated as the difference between the skills requirement for a given occupation and the modal education level of the unemployed youth. It means that for each occupation i, we would obtain the skills requirement using education levels as a measure of skills R, which we would compare with the modal education level of the unemployed youth. Therefore, for any occupation i, the skills gap is:

#### $Occupation skill gap=Y-R \tag{7}$

When the occupational skills gap is positive, it means that a typical youth who is unemployed has the skills required for the identified occupation while a negative occupation skills gap shows that a typical unemployed youth does not have the skills required for the occupation identified.

#### 4.7 Data Sources

The analysis in this study was informed by multiple data sets obtained from the following secondary sources: The World Bank Enterprise Survey 2018; Kenya Integrated Household Budget Survey (KIHBS) 2015/16; Census of Industrial Production, 2010; Occupational Information Network (O\*NET); and Economic Surveys and Statistical Abstracts.

The World Bank Enterprise Survey data was collected in Kenya between May 2018 and January 2019 with private firms within the non-agricultural economy as the unit of analysis. The sample for the survey was selected using stratified random sampling and stratification was done at three levels: industry, establishment size, and region. Our focus was 8 firms involved in manufacture of pharmaceuticals, 6 in wholesaling of pharmaceuticals and 6 in retail distribution of pharmaceuticals, respectively. The variables of interest from this data set were: firm size, main product/service ISIC code, registration status, ownership status, export as a percentage of total sales, and type of certification the firm has. In addition, we looked at variables such as access to finance, skills shortage, competition from unregistered firms as proxies for the business environment for these firms.

The Kenya Integrated Household Budget Survey (KIHBS) 2015/16 data was collected over a period of 12 months with households in Kenya as the unit of analysis. The data collected was on household characteristics, housing conditions, education, general health characteristics, nutrition, household income and credit, household transfers, information communication technology, domestic tourism, shocks to household welfare and access to justice. The variables of interest for

our study from this data set were: age, level of education, employment status, characteristics of the main occupation based on Kenya National Occupation Classification Standards (KNOCs), and the economic activity associated with the main job. Classification of economic activity is based on the 2008 edition of the UN International Standard Industrial Classification (ISIC- Rev 4) of all economic activities.

Census of Industrial Production (CIP) data was collected from November 2010 to April 2011 with the aim of providing detailed information on the structure of industrial activities in Kenya. The unit of analysis was establishments in mining and quarrying; manufacturing; electricity, gas, steam, and air condition supply; and water supply including sewerage and waste management activities. Our focus from this data set was establishments involved in manufacture of pharmaceuticals. The variables of interest from the census include: number of establishments, general particulars, economic activity and ownership, employment and hours worked, production and installed capacity, capacity under-utilization, inventories, expenditure on goods and services, cost of purchase of goods for resale, total expenditure, sales and other revenues, plant and technology in use, IT infrastructure and related services, research and development and fixed assets.

Occupational Information Network (O\*NET) is an online database containing over 1,000 occupations within the US. O\*NET maps occupations to a standardized database of information such as knowledge, skills, abilities, and education required for those employed in these roles. Although this data was initially constructed using inputs of occupational analysts, it is continually updated based on survey response from workers in each occupation and occupation specialists. The database uses the Standard Occupational Classification (SOC).

## 5. Findings and Discussions

## 5.1 Mapping of the Pharmaceutical Industry Value Chain in Kenya



Sources: Author's construct based on World Bank (2019)

## 5.2 Explanation of Pharmaceutical Value Chain

Kenya's pharmaceutical industry value chain has 3 main segments: manufacturing, which involves synthesis of finished drugs for wholesale distribution or consumption by the end user; wholesaling, which entails purchase of finished pharmaceutical products in bulk from manufacturers and storing them in warehouses for distribution to dispensing agents such as pharmacies and hospitals; and retailing where pharmaceutical products are made available for the final consumer at their point of need through retail outlets, pharmacies, chemists, shops, and health facilities.

## 5.2.1 Manufacturing

## Value adding activities

The manufacturing segment represent 64 per cent of the total value added within the pharmaceutical value chain in Kenya. It is the second largest in terms of contribution to wage employment within the pharmaceutical value chain, accounting for 4,322 jobs in 2018. Value adding activities in manufacturing include research and development; primary manufacturing; secondary manufacturing;
and tertiary manufacturing. A mapping of pharmaceutical firms in Kenya shows that 30 out of 34 Pharmacy and Poisons Board (PPB) registered manufacturing firms participated in secondary manufacturing of pharmaceutical products. Two firms participated in both secondary and tertiary manufacturing while only 1 firm participated in research and development, and primary manufacturing of drugs.

#### Research and development

Research and development is a critical component of drug manufacturing consisting of two value adding stages.

First, drug development which focuses on identification, screening of new chemical entities, and synthesis of drugs. Other aspects of drug development include exploring alternative methods of administering drugs, such as injections, or oral administration; reverse engineering of originator drugs to produce generic drugs; and combining existing medicaments into single dosage forms. An analysis of the pharmaceutical industry in Kenya shows that there is limited participation of pharmaceutical manufacturing firms in research and development especially when it comes to development of drugs. The few firms that have research and development departments focus on reverse engineering of generic products.

Second, clinical trials is further divided into 3 progressive phases. Phase I involves testing a new medication to evaluate its safety profile. In Phase II, the drug is tested on a few volunteers who have the disease or condition to see how well the drug treats the targeted disease. Phase III tests the medication on greater numbers of patients to confirm that the drug being tested, despite its clinical benefits, has no side effects on the wider population. Kenya is actively involved in clinical trials for multinational companies; therefore, it has put in place policy and legislative protections to safeguard citizens from the potential adverse effects of clinical trials. To this end, the PPB developed Guidelines for Conducting Clinical Trials in Kenya in 2016 which were revised in 2020 with a separate guideline for handling clinical trials during the COVID-19 pandemic released.

The guidelines gives PPB the mandate to: approve pharmaceutical products before they are rolled out for clinical trials; authorize conduction of clinical trials by individuals on successful making of a clinical trial application to the board; ensure that persons granted approvals shall put up robust quality assurance systems to ensure integrity of data generated, safety and well-being of study participants; prescribe guidelines for evaluation of applications made to be implemented for accelerated evaluations during emergency situations, epidemics and outbreak; and carry out inspections of clinical trials to ensure compliance of the trials with the prescribed requirements. Kenya has put in place various frameworks to govern research and development in the pharmaceutical industry in line with the global call for countries to support research and development of vaccines and essential medicines necessary for communicable and non-communicable diseases (SDG 3b). The Science and Technology (Amendment) Act of 1979 later amended to Science, Technology, and Innovation (STI) Act No. 28 of 2013 is the main Act governing research activities in Kenya. It puts in place frameworks for the establishment of Kenya Medical Research Institute (KEMRI) which is the main government body charged with carrying out research on human health. KEMRI has been recognized as a leader in research and development and was proven a key player in the fight against COVID-19 through the development of a rapid test kit.

For those in the private sector, the Act stipulates that they shall not undertake medical research without obtaining a license from the PPB, which is responsible for clinical trial approvals, oversight, and inspections, and a research permit from the National Commission for Science, Technology, and Innovation (NACOSTI). Some of the private medical research institutions include medical departments of universities and private research institutions. There has been notable progress in line with research and development by the private sector as well. For example, within the private sector, the Institute for Primate Research recently developed a HIV prevention gel which met international quality and ethical standards.

The STI Act No. 28 of 2013 is complemented by the Trademarks Act No. 7 of 2007 and the Intellectual Property (IP) Act, 2001. They put in place frameworks for protection of inventors in this space by outlining requirements for patenting and trademarking of inventions. The IP Act, 2001 also put in place frameworks for the establishment of the Kenya Industrial Property Institute (KIPI) mandated to administer industrial property rights.

#### Primary manufacturing

This is the second level under manufacturing. It entails the production of raw material such as Active Pharmaceutical Ingredients (APIs) or bulks, excipients, and packaging materials which are used in the manufacture of pharmaceutical products. APIs are classified into natural and synthetic products, where natural products are from animal and plant sources while synthetic products are produced through advancements in technologies. Value addition in production of APIs include synthesis of inorganic chemical substances; fermentation of microorganic cultures; and extraction of vegetable and animal tissues.

Kenya imports 80-90 per cent of APIs in both processed and unprocessed form. The aggregate value of the imports and exports for these products were Ksh 100 million and Ksh 90 million, respectively (Figure 3). Imports increased from Ksh 2.4 million in 2007 to Ksh 38.2 million in 2011 before decreasing to Ksh 6.4 million in 2018. Exports exhibited a similar trend and increased from Ksh 4.9 million in 2007 to Ksh 46.6 million in 2011 before decreasing to Ksh 5.4 million in 2018.



Figure 3: Imports and exports of processed and unprocessed APIs in Kenya between 2007 and 2018 in millions of Ksh

*Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. NB:* TC calculations based on UN COMTRADE statistics until January, 2011



Figure 4: Importer and average value of exports of processed and unprocessed APIs between 2007 and 2018

Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011 NB: TC calculations based on UN COMTRADE statistics until January, 2011

Majority of processed and unprocessed APIs are imported from India and United States of America, which account for the highest annual average value of imports at Ksh 3.11 million and Ksh 2.82 million (Figure 5). Other countries that Kenya imports from are Korea, Thailand, Germany, and South Africa. The top export destinations for processed and unprocessed APIs are from Uganda with exports valued at Ksh 3.7 million and Tanzania at Ksh 3.11 million.

## Figure 5: Tree map of exporter and average value of imports of processed and unprocessed APIs between 2007 and 2018



*Sources: ITC calculations based on Kenya national bureau of statistics, statistics since January, 2011*.NB: ITC calculations based on UN COMTRADE statistics until January, 2011

The other raw material processed at primary manufacturing stage alongside APIs are pharmaceutical blood products . In Kenya, the aggregate value of imports and exports from this product between 2007 and 2018 was Ksh 62.4 billion and Ksh 8.98 billion (Figure 6). Imports have shown an upward trend and increased from Ksh 1.48 billion in 2007 to Ksh 9.1 billion in 2015 before decreasing to Ksh 6.1 billion in 2018. Exports exhibited a similar trend and increased from Ksh 441 million in 2007 to Ksh 1.31 billion in 2013 before decreasing to Ksh 667 million in 2018.

Blood products are majorly imported from Belgium, India, and Denmark with the annual average value of imports at Ksh 1.88 billion, Ksh 1.28 billion and Ksh 880 million, respectively (Figure 8). Other countries that Kenya imports from are France, Germany, United States of America, United Kingdom, South Africa, Netherlands, and Switzerland. The top export destinations for blood products are Somalia with exports valued at, on average, Ksh 250 million, Uganda at Ksh 220 million, and South Sudan at Ksh 90 million, annually.

#### Secondary manufacturing

This is the third level of manufacturing, which involves combining raw materials to produce pharmaceutical products in a process known as formulation. In Kenya, 30 out of 34 PPB registered manufacturing firms are involved in secondary manufacturing of pharmaceutical products. Most of these firms focus on formulation of simple drug formulations such as antibacterial medicine, antiinfective medicine, analgesics, vitamins, coughs, and cold preparations instead of higher value medicinal products. Specifically, expensive innovative medicines such as anticancer and immunosuppressive drugs which have a big market share within the East Africa region are exclusively imported. At the same time, secondary manufacturing is limited to production of simple dosage forms such as



Figure 6: Imports and exports of blood products in Kenya between 2007 and 2018 in billions of Ksh

Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. ITC calculations based on UN COMTRADE statistics until January, 2011



Figure 7: Importer and average value of exports for blood products between 2007 and 2018

Sources: ITC calculations based on Kenya national bureau of statistics, statistics since January, 2011. ITC calculations based on UN COMTRADE statistics until January, 2011

Figure 8: Tree Map of Exporter and Average Value of Imports of Blood Products between 2007 and 2018



Sources: ITC calculations based on Kenya national bureau of statistics, statistics since January, 2011. NB: ITC calculations based on UN COMTRADE statistics until January, 2011 plain tablets and capsules. Only three firms are involved in production of complex dosage forms such as injectable infusions and ophthalmic formulations that require advanced technology for production.

### Tertiary manufacturing

Tertiary manufacturing is the fourth level and it encompasses packaging of finished products, repackaging of bulk finished products, drug labeling, and marketing of the drug. Packaging is typically done in three layers. The first covers the actual drug in finished form, the second used to use primary packages of the drug, and the third used to package drugs in bulk handling and warehousing. Drug labelling is the way that drug manufacturers communicate important information to prescribers, including health care professionals and pharmaceutical technicians (Gruber and Marshall, 2018). The information communicated at this stage may include product name, dosage, storage temperature, and expiry dates.

Primary, secondary, and tertiary manufacturing of drugs in Kenya is governed by various legislations and policies. The Kenya Narcotic Drugs and Psychotropic Substances (Control) Act No. 4 of 1994 puts in place regulations around drugs that can be manufactured privately and those that remain the responsibility of the government in line with the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Importation of pharmaceutical products is strictly limited to those registered under the Ministry of Health. For this reason, those not included in this listing are included in Imports, Export and Essential Supplies Act Cap. 502 under import restrictions. Those imported are due a tax exemption as is specified under the Value Added Tax Act, 2013. Like other products manufactured within the country or imported from other countries for sale locally, the levels are governed by the Standards Act No. 7 of 2004. The Act puts in place frameworks for the establishment of the Kenya Bureau of Standards (KEBS), which assists in ensuring that drugs produced in Kenya comply with international standards. In collaboration with the PPB, KEBS ensures that the importers of APIs obtain Certificates of Conformity (CoC) for their cargo before applying for Import Permits from PPB.

The most imported and exported pharmaceutical products are medicaments for therapeutic or prophylactic uses put in measured doses for retail sale. These medicaments have gone through all stages of pharmaceutical manufacturing including tertiary manufacturing. Imports increased from Ksh 18 billion in 2007 to Ksh 46.19 billion in 2018 while exports only increased from Ksh 5.9 billion to Ksh 11.9 billion in the same period (Figure 9).





Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. NB: ITC calculations based on UN COMTRADE statistics until January, 2011

The aggregate value for imports and exports for the period 2007 to 2018 was Ksh 435.36 billion and Ksh 111.63 billion, respectively (Figure 2). The medicaments imported and exported include those containing antibiotics; penicillin or derivatives thereof; hormones and steroids; provitamins and vitamins; corticosteroid hormones and their derivatives; insulin; pseudoephedrine; ephedrine; and alkaloids. Majority of these pharmaceutical products are imported from India, which had the highest annual average value of imports standing at Ksh 18.55 billion. Notably, South Africa is the only country in Africa that Kenya imports from, with imports valued at Ksh 1.3 billion (Figure 11). The top export destinations for medicaments are Tanzania, Uganda, Rwanda, Somalia, and Ethiopia who imported pharmaceutical products from Kenya worth, on average,



Figure 10: Importer and average value of exports for medicaments in measured doses between 2007 and 2018

Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. NB: ITC calculations based on UN COMTRADE statistics until January, 2011

Ksh 2.84 billion, Ksh 2.19 billion, Ksh 870 million, Ksh 490 million, and Ksh 430 million, respectively annually between 2007 and 2018. Other export destinations include Malawi, Zambia, Sudan (before 2012), South Sudan (post 2012), India, Democratic Republic of Congo, and Nigeria.

Generally, both exports and imports have exhibited an upward trend since 2007. However, aggregate pharmaceutical imports stood at about 4 times the value of all pharmaceutical exports in 2018. The value of Kenya's imports grew from Ksh 22.21 billion in 2007 to Ksh 55.84 billion in 2013. Exports grew from Ksh 6.97 billion to Ksh 13.01 billion during the same period.

Other pharmaceutical products that are imported and exported include surgical and wound dressings, and pharmaceutical preparations. The aggregate value of the imports and exports for these products was a combined total of Ksh 25.81 billion and Ksh 3.03 billion, respectively (Figure 13).

Figure 11: Tree map of exporter and average value of imports of medicaments in measured doses between 2007 and 2018



*Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011.* NB: ITC calculations based on UN COMTRADE statistics until January, 2011

Figure 12: Imports and exports of pharmaceutical products in Kenya between 2007 and 2018 in '000 US dollars



Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. NB: ITC calculations based on UN COMTRADE statistics until January, 2011



## Figure 13: Aggregate value of imports and exports by product between 2007 and 2018

Sources: ITC calculations based on Kenya National Bureau of Statistics, statistics since January, 2011. NB: ITC calculations based on UN COMTRADE statistics until January, 2011

The World Bank Enterprise Survey 2018 looked at firm characteristics for 8 firms in 2018, 4 of which were large enterprises while 4 were medium enterprises. The manufacturing node was found to be highly formalized with all 8 firms reporting that they were registered at the point they began operations. Three (3) were registered as limited liability companies, 1 as a shareholding company with tradable shares, 2 as shareholding companies with non-tradable shares and 2 as sole proprietorship. Based on this information, informality in the sector does not appear to be a major challenge hindering productivity and decent employment within the node. 1 of the firms had international quality certification, it complied with ISO 9001:2008 quality standard. Of the 8 firms surveyed, 4 firms reported direct exports of between 1 per cent of total sales and 20 per cent of total sales of finished pharmaceutical products. Five (5) of the firms reported having imported material inputs and supplies. Six (6) of the 8 firms surveyed was aged above 15 years. Older firms generally tend to be better placed to manoeuvre the business environment of a country.

## 5.2.2 Wholesaling

This is the second stage in the pharmaceutical value chain, accounting for 18 per cent of value addition. In terms of wage employment, wholesaling is the least contributor to total employment within the pharmaceutical industry in Kenya, accounting for 2,184 jobs in 2018.

Wholesale distribution in Kenya is undertaken by the public sector and private sector, including non-governmental organizations. For the public sector, Kenya Medical Supplies Authority (KEMSA), which is established under the KEMSA Act 2013 is charged with procuring, warehousing and distributing drugs and medical supplies to national and county government facilities. For the private sector, Mission for Essential Drugs and Supplies (MEDS), which is a faithbased non-profit organization, oversees the procurement, product identification, warehousing, logistics and distribution of health commodities and technologies. MEDs also provides services in prequalification of suppliers and inspection of commodities. Non-governmental organizations are also a source of donation drugs.

The government through the PPB produced national guidelines on Good Distribution Practices (GDP) Medical Products and Health Technologies in 2018. The policy document prescribes guidelines for establishment of both private and government distribution entities, quality management system, personnel handling stored pharmaceutical products, and infrastructural requirements for warehousing and storage premises, among others. Finished pharmaceutical products such as inputs to secondary manufacturing of pharmaceuticals are tax exempt for wholesalers as is specified under the Value Added Tax Act, 2013.

For donated drugs, the World Health Organization has developed guidelines aimed at protecting recipient countries, enhancing the responsibility and involvement of recipients in the process, and enhancing desirability of countries to develop a national medicine donations policy. Kenya has, however, not developed a local policy to guide activities in drug donations. Drug donations within the country are stored in various non-governmental warehouses that are expected to meet the standards outlined in the national guidelines on Good Distribution Practices (GDP).

The World Bank Enterprise Survey 2018 looked at firm characteristics for 6 firms that deal in wholesale distribution of pharmaceutical products. 50 per cent are medium enterprises (20-99 employees) enterprises and 50 per cent are small enterprises (5-9 employees). The distribution node was found to be highly formalized with 83.33 per cent of firms surveyed having been registered at the point of establishment. Majority of the firms (66.7%) were established as limited

liability partnerships while 33.3 per cent were sole proprietorships. None were established as tradable or non-tradable shareholding companies.

Also, all the companies had private domestic ownership above 75 per cent, 83.3 per cent of the businesses had ownership of above 75 per cent from a single family, and 16.67 per cent have females in the ownership with ownership of between 25 and 50 per cent. All the six (6) companies are aged between 11 and 30 years. Only 16.7 per cent had an internationally recognized quality certification.

## 5.2.3 Retailing

Retailing contributes 19 per cent of value addition within the pharmaceutical industry in Kenya. This segment is critical to the attainment of Universal Health Coverage through provision of pharmaceutical products to the end user at affordable prices, hence contributing to protection from financial hardships brought about by out of pocket expenditure on pharmaceutical products. In terms of employment, retailing is the highest contributor to total wage employment within the pharmaceutical industry in Kenya accounting for 5,760 jobs in 2018.

Like all other segments of the value chain, it is highly regulated. The Kenya Narcotic Drugs and Psychotropic Substances (Control) Act No. 4 of 1994 is one of the main Acts governing this node. It lists drugs to be considered under Schedule 1-4 with categorizations based on the Kenya National Drug Policy, 1994.

Schedule	Alternative Name	Description
Schedule I	Prescription Only Medicine (POM)	Prescription from a registered medical practitioner, dentist, or veterinary surgeon is required. Such drugs may be dispensed in limited quantities without prescription only by a registered pharmacist and only in an emergency, where a registered practitioner is not available
Schedule II	Pharmacy Only Medicines (P)	Prescription from an authorized prescriber is required
Schedule III		Drugs in this Schedule will be dispensed by a registered pharmacist without a prescription or by a pharmaceutical technologist on prescription from any authorized prescriber
Schedule IV	Over the Counter Medicines (OTC)	OTC medicines will be sold in authorized outlets without a prescription

Table 2: Categorization of drugs under Schedule 1-4 based on theKenya National Drug Policy, 1994

Source: Kenya National Drug Policy 1994

In line with administration of drugs, the Ministry of Health has established the Medical Practitioners and Dentists Act No. 12 of 2012. The Act stipulates that for a person to be registered as a medical or dental practitioner, they must be a holder of a degree, diploma or other qualification which is recognized by the Medical Practitioners and Dentists Board, which is established under the Act. It bans medical and dental professionals from recovering fees from patients for medical advice or medicine prescribed unless they are registered as a private practice. It also bars the unregistered and unlicensed practice of medicine, surgery and dentistry including prescribing medication. The PBB issues licenses pharmacies, medical facilities including hospitals, clinics and dispensaries, and shop outlets permitted to sell over the counter pharmaceuticals.

The Act is complemented by the Ministry of Health's National Standard Treatment Guidelines, which were last updated in 2009. Financing of drugs at the point of dispensing is done in part by the National Treasury which through the Ministry of Health budgets for drugs in the national Essential Medicines List (EML). The National Health Insurance Fund also caters for the cost of dispensed medicines as part of its "SUPA Cover" Benefit Package and through social protection programmes for health such as the Health Insurance Subsidy Programme for Orphans and Vulnerable Children.

The World Bank Enterprise Survey 2018 looked at firm characteristics for 8 firms that deal in retail of pharmaceutical products. 50 per cent are medium enterprises (20-99 employees) enterprises and 50 per cent are small enterprises (5-9 employees). The retail node was found to be highly formalized with all firms surveyed having been registered at the point of establishment. Majority of the firms (75%) were established as limited liability partnership while 12.5 per cent were sole proprietorships and partnerships. None were established as tradable or non-tradable shareholding companies. All the companies had private domestic ownership above 75 per cent, 87.5 per cent of the businesses had ownership of above 75 per cent from a single family, and 75 per cent have females in the ownership with 66.67 per cent having ownership of between 25 and 50 per cent. 50 per cent of the companies are aged between 11 and 30 years; and 50 per cent are below 10 years.

#### 5.3 Constraints to Growth of the Pharmaceutical Industry

The pharmaceutical industry in Kenya faces a range of constraints and challenges that limit its ability to meet domestic and regional demand for medicines and other pharmaceutical products while contributing to employment creation. The key challenges identified from this analysis are classified as per the nodes and activities identified within the pharmaceutical value chain as follows:

#### 5.3.1 Constraints at manufacturing node

Manufacturing of pharmaceuticals plays a fundamental role within the pharmaceutical industry value chain. However, it is faced with several constraints which hinder its overall performance. Some of the constraints identified include:

#### Low compliance with WHO Good Manufacturing Practices

Activities within the pharmaceutical industry are governed by a set of principles that provide a basis for safeguarding the quality and identity of pharmaceutical products at each segment of the value chain. These practices are outlined by the World Health Organization (WHO) and are internationally accepted as good practices for activities within the pharmaceutical value chain. At the global level, WHO is responsible for enforcing Good Manufacturing Practices (GMP) whereas the National Regulatory Authorities enforce the pharmaceutical industry practices at the national level and ensure that every firm within the pharmaceutical value chain adheres to these practices before licensing them to operate. The practices include: GMP which covers activities within pharmaceutical manufacturing; and Good Distribution Practices (GDP), which cover activities within wholesaling and retailing activities.

Before starting operations as a pharmaceutical manufacturing firm, an entity must first undergo inspection by the PPB to obtain a Kenyan GMP compliance certificate. This certificate is renewed after five years and can be revoked at any time should a firm fail to meet the set standards. In addition to attaining the Kenyan GMP standards, firms need to ensure that they upgrade to WHO GMP compliance, which is the internationally recognized standard.

For most firms in Kenya, the cost of upgrading to WHO GMP compliant standards is prohibitive. For instance, a medium to large firm would require about US\$ 5-10 million. This is half the cost of putting up a new manufacturing firm (about US\$ 10-20 million). In addition, such firms would require personnel who have the technical knowledge of how to design, upgrade and run WHO GMP compliant facilities. In most cases, this line of expertise is not available in the labour market. As such, firms who have upgraded or those who intend to upgrade must incur additional costs either to train their existing staff on GMP compliance or to outsource personnel familiar with these processes. Outsourcing staff has an additional cost implication, for instance of relocation costs especially in cases where firms use foreign labour. All these costs associated with WHO GMP compliance change the cost structure for GMP compliant firms, often forcing them to revise

their business model to compete favourably with other firms in the market who have not adhered to WHO GMP and have no additional GMP compliance related costs in their production costs.

Consequently, the poor WHO GMP compliance of Kenyan manufacturing firms makes them ineligible to bid for tenders in donor funded markets where WHO GMP compliance is a prerequisite for participation in the tendering process. So far, it is only one firm in Kenya which is WHO compliant; one other firm is almost attaining full WHO GMP compliance.

#### Access to finance

Pharmaceutical firms experience an acute problem in accessing finance at all levels in the value chain. Using the World Bank Enterprise Survey 2018, we find that 76 per cent of the manufacturing firms surveyed could not access the required finance for technological upgrade and current operations, with 13 per cent of the firms indicating that it was a very severe obstacle; 25 per cent reporting it as both a major and moderate obstacle; and only 13 per cent reporting it as a minor obstacle (Figure 14). Although 84 per cent of firms in wholesaling of pharmaceuticals indicated that access to finance was an obstacle, most of the firms (67%) considered it a minor obstacle with only 17 per cent indicating that it was a major obstacle. For retailing activities, 64 per cent of the firms considered it an obstacle with 38 per cent reporting that it was a moderate obstacle.

## Figure 14: Access to finance as an obstacle for firms in the pharmaceutical value chain in Kenya



#### Source: Authors' own construct based on World Bank Enterprise Survey, 2018

From this analysis, it is evident that although access to finance is a challenge for firms in the pharmaceutical industry, it is more severe for firms involved in manufacturing activities. This is attributed to the intricate interrelationship between finance, technological capability upgrading, innovations and access to markets for pharmaceutical firms. The intricate relationship calls for development of a compelling business model to convince financial institutions of the viability of the firm's projects.

Access to finance as a constraint is further compounded by the fact that most pharmaceutical manufacturing firms in Kenya are not WHO GMP since most investors consider compliance to WHO GMP as an indication of the risk profile of firms. Specifically, donors are reluctant to invest in non-compliant firms due to the perception that they pose higher risks in comparison to WHO GMP compliant firms. This selective investment based on a firms' compliance with GMP standards makes it harder for firms, especially those who are not GMP compliant, to access funds to improve their quality and expand their sales to donor markets, which require GMP compliance as a prerequisite.

Consequently, access to finance deters manufacturing firms from investing in skills upgrading and training for their staff especially when it comes to trainings related to identification and correction of potential areas of quality and safety lapse with regard to the manufacture of medicines. Further, financial constraints hinder manufacturing firms from carrying out bioavailability and bioequivalent studies.

Analysis from the World Bank Enterprise Survey 2018 (Figure 15) shows that access to finance as an obstacle is inversely related to firm size. All medium sized firms (those with 20-99 employees) considered it as an obstacle with 20 per cent citing that it was a very severe obstacle; 20 per cent as a major obstacle; 40 per cent moderate; and 20 per cent as a minor obstacle. For large firms (those with over 100 employees), only 33 per cent indicated that access to finance was a major obstacle.







#### Limited access to markets

Market for pharmaceutical products is broadly classified into domestic and export markets. The domestic market is further broken down into the private and public market, and non-government organizations and donor markets. In the private domestic market, access to markets is limited due to the stiff competition that local manufacturers face, which is in two folds: first, most local manufacturers of pharmaceuticals have similar production portfolio, which involves production of simple drug formulations such as antibacterial medicine, analgesics, vitamins, coughs and cold preparations. Therefore, they compete for the domestic market with other local manufacturers who also produce similar products.

In the public market, KEMSA is the national procurement agency responsible for procuring medicine for the government. The Public Procurement and Disposals Act, 2012 allows a margin of preference of 15 per cent in public procurement for goods manufactured in Kenya to support market access. However, the agency has not fully implemented this legislation, citing lack of clear guidelines from the National Treasury. As such, access by the local manufacturing industry to the public market is still limited.

In the market funded by donors, for instance the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the US President's Emergency Plan for AIDS Relief (PEPFAR), purchase of drugs is through a competitive bidding process in which WHO GMP pre-qualifications are needed. So far, only one firm in Kenya has attained WHO GMP complianc; therefore, it means it is the only firm that can take part in competitive bidding for donor funded markets and all the other firms are automatically locked out of the donor funded markets.

Access to the export market especially within the East African Community has been declining since 2014. The country has recorded a decline in exports to Rwanda, Tanzania and Uganda who are the major importers of pharmaceutical products. Exports to Rwanda decreased by 43 per cent from Ksh 1.36 billion in 2014 to Ksh 0.77 billion in 2018. In Tanzania, the value of exports reduced by 32 per cent from Ksh 4.08 billion to Ksh 2.78 billion while in Uganda, exports reduced by 21 per cent from Ksh 2.702 billion to Ksh 2.125 billion from 2014 to 2018. This is in part due to the rapid expansion in domestic demand for pharmaceuticals within countries in the region, which has increased their volume of imports making them better positioned to take advantage of the price discounts offered by China and India for importation of full load containers of pharmaceutical products. At the same time, most countries within EAC are developing their pharmaceutical industries with the intention of boosting local production of pharmaceutical products to reduce their reliance on pharmaceutical imports.

#### Lack of competitiveness

Local manufacturers of pharmaceuticals face competition from imported pharmaceutical products. The domestic demand for pharmaceutical products is price elastic and imports from China and India have a comparative and competitive advantage when it comes to pricing their products within the Kenyan market. This is because these countries have well established pharmaceutical industries, and they enjoy economies of scale; therefore, they incur relatively lower production costs in comparison to local manufacturing firms. As a result, they can sell their products at significantly lower prices but still cover their operation and production costs while enjoying high profit margins. Local manufacturing firms have high production costs and operate at about 53 to 63 per cent of their production capacity and therefore cannot afford to sell at low prices. As such, consumers opt to buy imported pharmaceutical products on account of their relatively lower prices.

#### Skills shortage

Skill shortage exits when employers cannot find workers with the ability to carry out tasks that are associated with a job from the labour market. The existence of skills shortage is a major bottleneck for firms operations within the pharmaceutical industry since the industry heavily relies on skilled and semi-skilled labour for its operations.



## Figure 16: Skills shortage as an obstacle for firms in the pharmaceutical value chain in Kenya

#### Source: Authors' own construct based on World Bank Enterprise Survey, 2018

Analysis from World Bank Enterprise Survey 2018 (Figure 16) shows that the problem of skills shortage is highest in manufacturing activities of the pharmaceutical value chain and lowest in wholesaling activities. 74 per cent of firms in manufacturing cited skills shortage as an obstacle with 5 per cent indicating that it was a very severe obstacle; 19 per cent as a major obstacle; 20 per cent as a moderate; and 30 per cent as a minor obstacle. These findings are in line with existing literature (National Skills Development Council Secretariat, 2017; UNIDO, 2019; EAC, 2018) that outlines skills shortage in pharmaceutical manufacturing as a key constraint within the industry.

The skills shortage in manufacturing firms is acute and it ranges from semiskilled jobs such as machine operators, quality controllers, and marketing and sales positions to highly skilled jobs such as industrial pharmacists, chemists, microbiologists, site supervisors and engineers. Firms in pharmaceutical manufacturing require technically qualified individuals to ensure safety, efficacy, and quality of products that meet the regulatory requirements for market approvals.





Source: Authors' own construct based on World Bank Enterprise Survey, 2018

Figure 17 shows that skills shortage as an obstacle to operations of firms within the pharmaceutical industry is directly related with firm size. 78 per cent of large firms indicated that it was an obstacle, with 33 per cent citing it as a major obstacle; 36 per cent moderate; and 9 per cent minor. On the other hand, 72 per cent of medium firms indicated that shortage of skills was an obstacle with 9 per cent reporting it as a major obstacle; 27 per cent as a moderate obstacle; and 36 per cent as a medium obstacle. A plausible explanation for this trend could be that large firms have bigger departments, and therefore their demand for labour will be relatively higher than other firms. If they cannot find individuals to fill these departments from the labour force, then they are more likely to be affected in comparison with medium firms.

#### 5.3.2 Constraints at distribution node

Pharmaceutical distribution channels in Kenya are broadly categorized into public, private and NGO who distribute both imports and locally manufactured pharmaceutical products. Our analysis of distribution of pharmaceuticals concentrates on distribution carried out by the private sector through wholesalers, sub-wholesalers, and retailers. The key constraints that hinder the operation of wholesalers and retailers include:

#### Poor compliance with WHO Good Distribution Practices

Good Distribution Practices (GDP) cover both wholesale and retail activities within the pharmaceutical industry value chain. For firms to commence operation either as wholesalers or retailers of pharmaceutical products, they must obtain a GDP compliance certificate from the PPB. The certificate is issued upon inspection by the Pharmaceutical GDP inspectorate who verify that the entities meet GDP guidelines. However, there has been laxity when it comes to enforcing local GDP compliance from a regulatory perspective. The GDP inspectorate is constrained in terms of adequate manpower to effectively conduct inspections in all wholesale and retail outlets countrywide. In addition, the inspectorate lacks the technical expertise to conduct regular inspections as many of its staff are pharmacist and pharmaceutical technologists who lack expertise in quality assurance matters in line with GDP guidelines.

At wholesale and retail firm level, laxity to attain WHO GDP compliance is in part due to the prohibitive financial cost associated with upgrading and the fact that there exists no international procurement contracts which call for compliance with GDP practices as a prequalification. To this end, firms do not see the economic value of incurring additional upgrading costs since they only supply the local market to which they meet the local GDP compliance standards. This argument is problematic especially since the industry seeks to take part in the pharmaceutical industry global value chain by expanding wholesale and retail activities to other markets, and this will call for global compliance to international practices.

Also, being WHO GDP compliant would entail firms investing in skills upgrading for most of their staff. This is because most staff in wholesale and retail firms are pharmacists and pharmaceutical technologists with a training that has a bias on clinical pharmacists and aspects directly related to dispensing of medicines to patients. However, when it comes to aspects related to quality assurance and quality management systems, which are needed for upgrading to WHO GDP compliance, these individuals lack the prerequisite technical skills. This is an additional cost that wholesalers and retailers are not willing to incur.

### Highly fragmented markets

The distribution of pharmaceuticals in Kenya mirrors that in most developing countries, which is characterized with many intermediaries between manufacturers of pharmaceuticals and patients. The country has about 700 wholesalers and sub-wholesalers and about 3,500 registered retail pharmacies who are skewed towards urban areas. Nairobi, for instance, has 26 retail pharmacies per 6 persons compared to North Eastern region, which has 0.4 per 100,000 people. High fragmentation of the market is a major challenge as it means wholesalers and retailers have a small volume base to recover their fixed costs. To counter this challenge, firms either down scale their fixed capital investments for instance in warehousing, skills development, and use of information technology or charge higher gross markups since every intermediary within the chain leads to an increase of about 25 per cent on the final price.

#### Competition from unregistered firms

Due to the existence of many wholesalers and retail outlets, the pharmaceutical GDP inspectorate is not adequately equipped in terms of manpower and technology to effectively monitor all the wholesale and retail outlets in Kenya. Statistics from a survey of the pharmaceutical industry in 2019 indicate that there are about 7,000 retail outlets within the country, out of which 50 per cent are unregistered. This high number of unregistered retail outlets is in part due to high fragmentation of distribution of pharmaceuticals, which makes it difficult for the pharmaceutical GDP inspectorate to effectively conduct market surveillance across the country.

Even in cases where unregistered outlets are identified, it is difficult to shut them down due to public hostility since in most cases these outlets are the only source of pharmaceutical products for the public. Further, the inspectorate is also constrained in terms of skilled manpower as the staff consists of pharmacists and pharmaceutical technologists who have no knowledge of inspection techniques, investigation methods and how to handle prosecution of firms found to be in operation without prerequisite license. As such, the market is flooded with products from unregistered outlets, which compete unfavourably with products from registered firms.

Analysis from the World Bank Enterprise Survey 2018 (Figure 18) shows that both firms in wholesale and retail firms consider competition from unregistered outlets to be a bottleneck for their operations. However, the constraint is most prominent in retail firms, with 74 per cent reporting it as an obstacle in comparison to the 64 per cent for wholesale firms. Further, the analysis shows that 17 per cent of retail firms consider competition from unregistered firms as a very severe constraint and 22 per cent report it as a major constraint. None of the wholesale firms surveyed reported it as a very severe challenge and only 13 per cent cited it as a major constraint.



Figure 18: Competition from unregistered firms

Source: Authors' own construct based on World Bank Enterprise Survey 2018

## 5.4 Job Creation Potential

## 5.4.1 Direct employment

Quantity of Jobs:

(i) Status of employment creation by pharmaceutical manufacturing

Employment in manufacturing of pharmaceuticals increased from 3,389 in 2007 to 4,322 in 2018. This is equivalent to an increment of 27.5 per cent, and a CAGR of 2.05 per cent. Employment in pharmaceutical manufacturing represents only 1.41 per cent of total employment in manufacturing in 2018. Earnings for the pharmaceutical industry have also grown steadily at a CAGR of 8.3 per cent.

(ii) Is it labour or capital intense? (Labour to value added ratios)

Comparatively, the manufacture of pharmaceutical products and pharmaceutical preparations is among the top six most labour intense industries among other manufacturing sub-sectors. Based on the Census of Industrial Production, 2010, 2.3 of employees are required to increase gross value added by Ksh 1 million.



## Figure 19: Labour to value added ratios for various manufacturing sub-sectors



(iii) Gender inclusion in the pharmaceutical manufacturing segment

The World Bank Enterprise Survey interviewed 5 firms (with a combined total of 745 employees), 10 firms (with a combined total of 886 employees) and 8 firms (with a combined total of 1888 employees) in manufacturing of pharmaceuticals in 2007, 2013 and 2018, respectively. The proportion of female-owned firms surveyed decreased from 100 per cent in 2007 to 37.5 per cent in 2018. However, the proportion of female workers employed in pharmaceutical manufacturing increased from 29.9 per cent to 44.4 per cent in 2018. Female employees in top management constituted 28.7 per cent in 2007, 44.2 per cent in 2013 and 28.6 per cent in 2018. Though there has been an improvement in participation of women in pharmaceutical manufacturing, it remains below parity at ownership, management, and employee levels. There is need to put in place strategies to enhance inclusion of women in pharmaceutical manufacturing.



Figure 20: Gender inclusion within pharmaceutical manufacturing

Source: Authors' own construct based on World Bank Enterprise Survey, 2018

(iv) Job creation potential (quantity of jobs): Employment elasticities and projections

The employment elasticity for manufacture of pharmaceuticals computed using the three waves of the World Bank Enterprise Survey was approximately 0.4. This implies that a 1 per cent increase in GDP contribution of the industry would increase employment by 0.4 per cent. With a projected compounded annual sector growth rate of between 7.6 per cent and 12 per cent between 2018 and 2023. The projected annual employment growth for the sector would range between a minimum of 3.04 per cent and 4.8 per cent. The average annual productivity growth would range from between 4.56 per cent and 7.2 per cent.

#### Table 3: Regression results from elasticity approach

Dependent variable: Log (employment in pharmaceutical	Coefficient
manufacturing firms)	
Log (value added)	0.3859***
	(0.030)
Constant	-2.6920***
	(0.512)
Observations	23
Number of panel_id	21

Robust standard errors in parentheses

\*\*\* p<0.01, \*\* p<0.05, \* p<0.1

At the current growth trajectory, it is expected that employment in pharmaceutical manufacturing would increase by 10.7 per cent to 4,784 employees. Under scenario one (1) with an elasticity of 0.4 and a potential annual employment growth rate of 3.04 per cent, the employment would increase by 16.2 per cent to 5,020 while under scenario two (2) with an elasticity of 0.4 and a potential annual employment growth rate of 3.04 per cent, the employment would increase by 26.4 per cent to 5,464.





Source: Authors' construct based on Kenya National Bureau of Statistics (2019), Various statistical abstracts

#### 5.4.2 Indirect employment

Employment in wholesale of pharmaceuticals decreased by 31 per cent from 3,165 in 2007 to 2,184 in 2018 (Figure 22). This is equivalent to a CAGR of negative 3.6 per cent and represented only 0.87 per cent of total employment in wholesale and retail in 2018. Earnings for the pharmaceutical industry have also decreased by 13 per cent. Employment in retail of pharmaceuticals has increased by 111 per cent from 2,596 in 2007 to 5,760 in 2018 (Figure 22). This is equivalent to a CAGR of 7 per cent and represented only 2.3 per cent of total employment in wholesale and retail in 2018. Earnings for the pharmaceutical industry also grew at a CAGR of 10.3 per cent.



Figure 22: Indirect employment within the pharmaceutical industry

Source: Kenya National Bureau of Statistics (2019), Various statistical abstracts

## 5.5 Skills Gap Analysis in the Pharmaceutical Industry

Skills is the ability to carry out a task. If skills requirements of a particular job do not exist within the target population, which is the unemployed youth, this is referred to as a skills gap. Our analysis of skills gap within the industry has been done at an industry level and at an occupational level as follows:

#### 5.5.1 Pharmaceutical industry skills gap

At an aggregate level, the pharmaceutical industry appears to have a skills surplus among the unemployed youth in the population (Table 4). However, skills availability reduces with an increase in the skills requirement. For the 4<sup>th</sup> and 5<sup>th</sup> skills levels particularly, skills availability ratios were below 10, indicating that attracting unemployed youth to the industry may be difficult.

Table 4:	Pharmaceuti	ical industry	y skills gaps	s analysis
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	1st Skills Level	2nd Skills Level	3rd Skills Level	4th Skills Level	5th Skills Level	Total
Skills Supply	31,090.60	0	16,618.10	8,107.70	2,922.70	58,739.10
Skills Demand	2,273.40	0	1,210	1,197.50	608.4	5,289.30
Research and Development	298	0	0	429	370	1097
Manufacturing	70	0	0	0	70	140
Wholesale	1438	0	429	0	0	1867
Retail	467	0	781	769	168	2185

Skills Gap	28,817.20	0.00	15,408.10	6,910.20	2,314.30	53,449.80
Skills Availability Ratio	13.68	N/A	13.73	6.77	4.80	11.11

Source: Authors' construct based on KIHBS, 20015/16 data

Occupational skills gap analysis for the pharmaceutical manufacturing (including Research and Development) node

Based on the current occupational profile of the pharmaceutical industry provided in Figure 23, there are 15 occupations that dominate pharmaceutical manufacturing, including research and development.





Based on this occupational profile, unemployed youth aged between 21 and 25 years whose modal years of schooling puts majority of them under skills level 3 (semi-skilled category) meet the labour demand market requirements for 6 occupations, namely: farm hands and related labourers; fortune tellers and other related occupations including witchdoctors; manufacturing labourers including machine operators; messengers, porters and watchmen; and field crop, vegetable and horticulture farm workers. All other age groups considered only meet the requirements for 2 occupations: fortune tellers and related occupations such as witchdoctors, and manufacturing labourers.

Though skills may be available in the general population, they may not match the requirements necessary to enhance the competitiveness of manufacturing sector and overcome challenges of skills shortages. The following is a mapping of occupations in pharmaceutical manufacturing based on best practices of Bangladesh:

Source: Authors' construct based on KIHBS, 2015/16 data



# Figure 24: Mapping of occupations in pharmaceutical manufacturing organized in order of hierarchy

Source: (Jalil, Ullah, Islam and Tareq, 2017)

Based on modal years of schooling outlined in the O\*NET Database, occupational gaps were computed for the occupations mapped above.

Occupation	Required Modal Years of Schooling based on O*NET Database	Occupational Skills Gap			
Management		15-20	21-25	26-30	31-34
Chief Executive Officer	18	-10	-6	-10	-18
Industrial Production Manager	16	-8	-4	-8	-16
Marketing Managers	16	-8	-4	-8	-16
Administrative Services Managers	12	-4	0	-4	-12
Professionals					
Biomedical Engineer	16	-8	-4	-8	-16
Chemical Engineer	16	-8	-4	-8	-16
Computer Hardware Engineer	16	-8	-4	-8	-16
Water and Waste Water Engineer	16	-8	-4	-8	-16

Table 5:	Occupational	skills gap	for pharma	ceutical	manufacturing
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Industrial Engineers	15	-7	-3	-7	-15
Biochemical Engineers	16	-8	-4	-8	-16
Biologists	18	-10	-6	-10	-18
Biochemists and Biophysicists	18	-10	-6	-10	-18
Microbiologists	16	-8	-4	-8	-16
Bioinformatics Scientists	16	-8	-4	-8	-16
Molecular and Cellular Biologists	18	-10	-6	-10	-18
Technicians					
Biological Technicians	16	-8	-4	-8	-16
Chemical Technicians	15	-7	-3	-7	-15
Inspectors, Testers, Sorters, Samplers, and Weighers	11	-3	1	-3	-11
Office and Administrative Support					
Secretaries and Administrative Assistants, Except Legal, Medical, and Executive	12	-4	0	-4	-12
General Office Clerks	12	-4	0	-4	-12
Plant and Machine Operators					
First-line supervisors/managers of production and operating workers	12	-4	0	-4	-12
Crushing, Grinding, and Polishing Machine Setters, Operators, and Tenders	12	-4	0	-4	-12
Mixing and Blending Machine Setters, Operators, and Tenders	12	-4	0	-4	-12
Heat Treating Equipment Setters, Operators, and Tenders, Metal and Plastic	12	-4	0	-4	-12
Separating, Filtering, Clarifying, Precipitating, and Still Machine Setters, Operators, and Tenders	12	-4	0	-4	-12
Packaging and Filling Machine Operators and Tenders	12	-4	0	-4	-12
Cooling and Freezing Equipment Operators and Tenders	10	-2	2	-2	-10

Based on the sample of occupations reviewed for this node, the occupations are either skilled, semi-skilled or unskilled in nature. The requirement in terms of modal years of schooling range between a maximum of 18 years of schooling for some management and professional level occupations and a minimum of 10 years of schooling for some plant and machine operators.

#### Management

The youth in the population were only qualified for one occupation sampled at management level. For those in management positions, the most preferred field of knowledge is business, administration, and management. Occupations in this category tend to have higher cognitive skill requirements than other categories of occupations within the pharmaceutical manufacturing industry. Some of the cognitive skills identified for occupations within this category are: critical thinking; active listening; reading comprehension; coordination; time management; monitoring; judgment and decision making; complex problem solving; social perceptiveness; management of personnel resources; active learning; and negotiation. In terms of practical skills, those in these occupations are expected to have speaking, writing, and reading skills. Digital skills required for individuals in occupations in this category include operation monitoring; technology design; and operation and control. The most commonly used technologies are as follows: accounting software for example Intuit QuickBooks; database user interface and query software such as Microsoft Access; enterprise resource planning ERP software such as Microsoft Dynamics; project management software.

#### Professionals

The youth in the population were only qualified for one occupation sampled at professional level. For professionals in the pharmaceutical manufacturing node, the most preferred field of knowledge is science mathematics and informatics. Occupations in this category have high requirements in terms of cognitive skills, albeit lower than occupations in management. The most preferred skills being reading comprehension; critical thinking; active listening; complex problem solving; judgment and decision making; active learning; and monitoring. The practical skills required by occupations in this category are science; speaking; mathematics and writing. These occupations require a higher level of digital skills than occupations in management, technicians, office administration and plant operator categories. The main digital skills required are operation monitoring; technology design; troubleshooting; programming; and operation and control.

#### Technicians

The youth in the population were only qualified for one occupation sampled at technician level. For technicians, the most preferred field of knowledge is science, mathematics, and informatics though with a lower complexity requirement than professionals in the pharmaceutical manufacturing node. Occupations in this category require less cognitive skills than in the previous two occupation categories. The most required are reading comprehension; critical thinking; and active listening. Practical skills required are writing; speaking; quality control analysis; and science. Like professionals in pharmaceutical manufacturing, a high level of digital skills is required with the main skills being: operation monitoring; operation and control; troubleshooting; and equipment maintenance.

## Office and administrative support

The youth in the population were qualified for all occupations sampled at office and administration level. For office and administrative support business, administration and management is the most preferred field of knowledge though it is required at a lower complexity than occupations in management. Occupations in this category require less cognitive skills than management, professionals, and technicians with the most preferred being active listening and reading comprehension. Practical skills most required are speaking and writing while the sole digital skill required is operational monitoring.

## Plant and machine operators

The youth in the population were qualified for all occupations sampled at plant and machine operator level. For plant and machine operators, the most required fields of study are education and training, and technology, production, and construction. These occupations do not require a significant level of cognitive skills and only require practical skills in speaking and quality control analysis. Digital skill requirements include: operation monitoring; operation and control; equipment maintenance; troubleshooting; equipment selection; and repairing.

## Occupational skills gap analysis for wholesale

For wholesale of pharmaceutical products, the occupational profile was constituted of 6 broad categories of occupations. Occupations within this category are majorly semi-skilled and unskilled in nature. The most common broad occupation in the node are those that relate to shop assistants and demonstrators. Based on the modal years of schooling for unemployed youth within the population, those aged 21-25 were suited to all broad categories of occupations while those aged 15-20, 21-25, and 31-34 were only suited to 4 occupations, namely those relating to: motor vehicle drivers; messengers, porters, watchmen and related workers; information professionals; and other sales and service labourers.

## Occupational skills gap analysis for pharmaceutical retail

For retail of pharmaceutical products, the occupational profile was constituted of 12 broad categories of occupations. Occupations within this category are skilled, semi-skilled and unskilled in nature. Like the wholesale node, the most common broad occupation in the node are those that relate to shop assistants and demonstrators. Based on the modal years of schooling for unemployed youth within the population, those aged 21-25 were suited to 4 broad categories of occupations while those aged 15-20, 21-25, and 31-34 were only suited to 1.



Figure 25: Occupational profile for wholesale of pharmaceutical products

Source: Authors' construct based on KIHBS, 2015/16 data





Source: Authors' construct based on KIHBS, 2015/16 data

## 6. Conclusion and Recommendations

## 6.1 Conclusion

The pharmaceutical industry in Kenya is made up of establishments involved in the process of discovering, developing, manufacturing, distributing, and marketing of drugs. A mapping of the pharmaceutical industry value chain shows that the level of participation of pharmaceutical firms across the value chain varies. Most firms participate in secondary manufacturing with a focus on producing simple drug formulations such as antibacterials, analgesics, vitamins, coughs, and cold preparations but they leave expensive innovative medicines such as anticancer drugs, immune-suppresive drugs, or blood components exclusively for importation. However, activities such as research and development, primary manufacturing and tertiary manufacturing attract minimal participation of local firms.

Constraint analysis shows that the industry is faced with several constraints, which inhibit its growth and overall job creation potential. The key cross constraints across the value chain include access to finance, compliance with WHO industry standards, lack of competitiveness and skills shortage. A comparison on the level of severity of these constraints across the value chain shows that they are most severe in the manufacturing activity of the pharmaceutical value chain.

When it comes to job creation potential, the industry portrays a direct and significant relationship between its growth in value added and employment creation. Specifically, the results from elasticity estimations show that a 1 per cent increase in gross value added in pharmaceutical manufacturing increases employment within the industry by 0.4 per cent. Using the World Bank projected industry growth rates of between 7.6 per cent and 12 per cent, employment in pharmaceutical manufacturing is expected to grow by a minimum of 16.2 per cent to 5,020 and a maximum of 26.4 per cent to 5,464 in 2023.

From skills gap analysis, the pharmaceutical industry has a skills surplus across all the skills levels. However, skills availability within the industry reduces with an increase in skills requirement. For the 4<sup>th</sup> and 5<sup>th</sup> skills levels particularly, skills availability ratios were below 10, indicating that attracting unemployed youth to the industry may be difficult.

## 6.2 Recommendations

To address the challenge of access to finance:

(i) Pharmaceutical industry associations could consider conducting forums with those in the financial sector.

The aim of such forums is to facilitate knowledge exchange and capacity building between those in the pharmaceutical industry and those in the financial sector, such as banks and microfinance institutions. During such forums, those from the pharmaceutical firms can be enlightened on ways of developing robust project proposals that highlight firms' capabilities, what the money is needed for, and how revenue will be generated to repay the loan.

Those from financial institutions need to be enlightened on pharmaceutical industry business dynamics, risks associated with the industry and the opportunities that the industry presents. In this way, they will be better informed in terms of assessing risk levels of firms within the industry and avoid generalization of the industry as high-risk. Also, financial institutions can consider employing those with a background in the pharmaceutical industry to build knowledge of the operational dynamics of the pharmaceutical industry.

(ii) The government could consider establishing a Pharmaceutical Development Fund

Pharmaceutical Development Funds are avenues for governments to provide direct capital provision to enhance access to finance for firms by providing low interest loans. Such a fund has successfully been set up in Ghana where in 2014, the government announced that it would set aside US\$ 20 million from the Export Development and Agriculture Investment Fund (EDAIAF) to be extended as soft loans to those within the pharmaceutical industry. The Government of Nigeria has also proposed a US\$ 100 million fund for the industry, but the fund has not yet been operationalized.

The Pharmaceutical Development Fund in Kenya can be established with the objective of mobilizing and directing financial resources for the development of the industry. Prior to establishment of this fund, consultations can be done between stakeholders within the industry, financial experts, those with experience in banking and those in the private sector. Among the issues that can be discussed during such consultations include:

- Ideal and sustainable funding mechanisms that can support the industry
- Strategies that will attract funding institutions
- Technical support for the management of the fund
- Guidelines on how those in the pharmaceutical industry will access the fund

The fund could be accompanied by technical support geared towards encouraging upgrading of firms to WHO compliance standards. This would act as an incentive for firms to upgrade to WHO compliance standards, thereby making them better positioned to attract investments from international investors such as
the International Finance Corporation (IFC) who consider compliance to WHO practices as a prerequisite for investment.

To address the challenge of skills shortage

(i) The government could consider facilitating international cooperation for local skills development

International organizations such as UNIDO provide support to developing human resources within the pharmaceutical industry with the objective of enhancing local production of pharmaceuticals. In Tanzania, for instance, UNIDO has supported a partnership between Saint Luke Foundation/Kilimanjaro School of Pharmacy in Tanzania and the US universities Howard and Purdue to conduct an Industrial Pharmacy Advanced Training (IPAT) programme which provided state-of-theart knowledge and skills on pharmaceutical production, regulatory affairs and research. The curriculum, which consists of four modules plus lab training and expanded to 11 modules for a Master's programme in 2014, is particularly well suited for obtaining practical skills and insights into the operational environment and processes of the pharmaceutical industry.

The government could work with UNIDO to set up a similar training programme for pharmacy students in institutions of higher learning to enable pharmacy students acquire industry specific training required for the industry. This would in turn contribute to the wider goals of embedding industrial pharmacy into the pharmacy education curriculum in institutions of higher learning and to strengthen the link between the academia and industry.

Also, the government could work with UNIDO in close consultation with those in the pharmaceutical industry and those in academia to assess the training needs of the pharmaceutical industry with the objective of developing a harmaceutical industry skills development strategy.

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