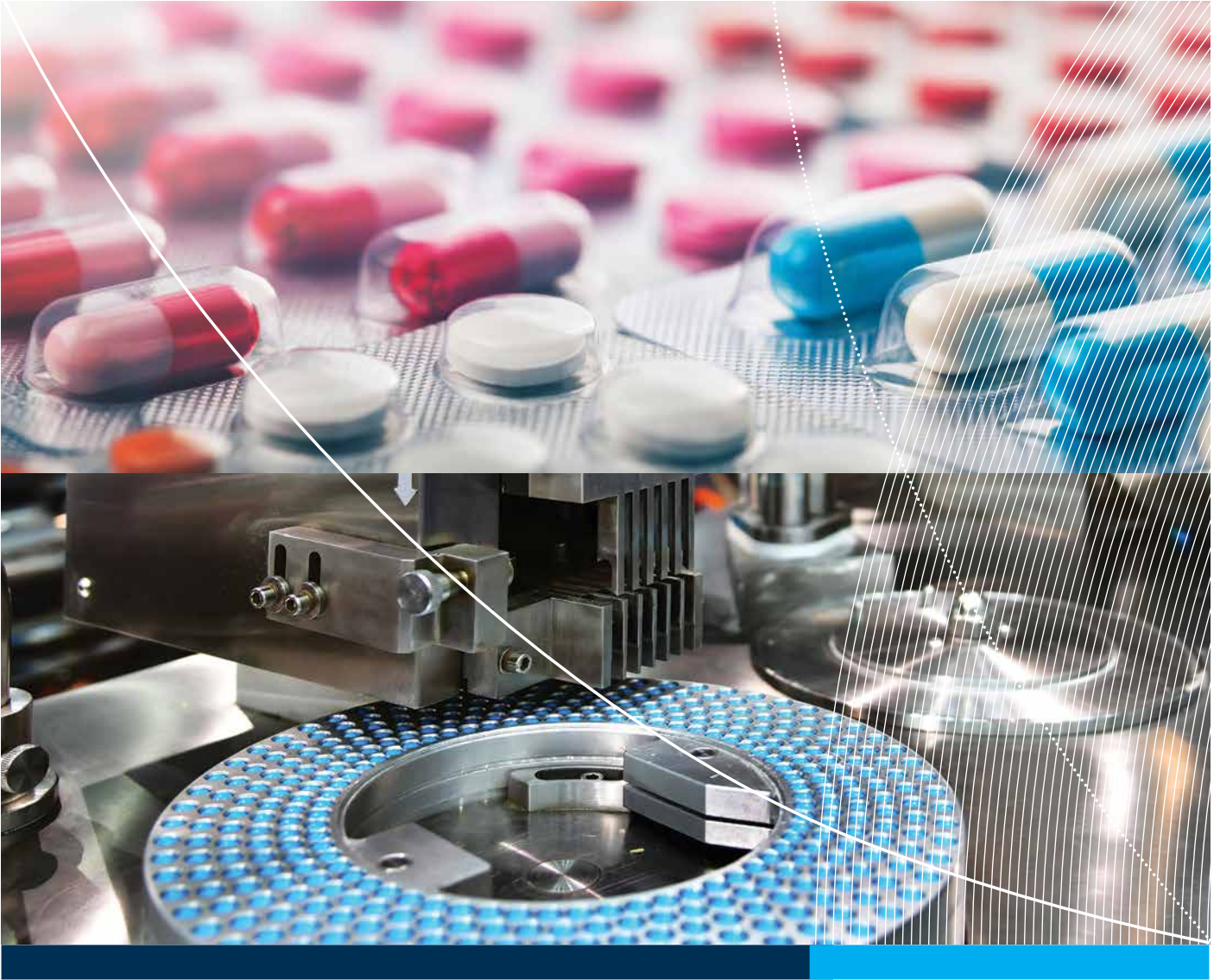




REPUBLIC OF KENYA

Ministry of Health

Ministry of Industrialization, Trade and Enterprise Development



Kenya Pharmaceutical Industry

DIAGNOSTIC REPORT 2020

PREPARED BY:



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FOREWORD



Kenya's Ministry of Health is responsible for protecting the public's constitutional rights to health and to access high-quality medical treatments. This includes providing oversight policies that promote pharmaceutical manufacturing in Kenya. The delivery of cost-effective pharmaceutical services to the population is underpinned by broad policy mechanisms, as stipulated in the Kenya National Pharmaceutical Policy. Medical products and health technologies are critical components of universal health care, which is a key pillar of the President's Big 4 Agenda, while pharmaceutical manufacturing is central to achieving economic growth and development.

The pharmaceutical sector directly affects Kenyan people's health and safety, while playing a significant role in the national economy, and driving international trade and cooperation. Therefore, it is critical for the government to strengthen the sector's institutions and regulations, and to support the development of specialized technical skills for the industry.

Kenya's pharmaceutical sector is affected by regional and international trends, such as growth of local industry, the country's role in regional and international trade in pharmaceuticals, related technological advancements, and global efforts to control and eliminate diseases. All these factors shape the direction of pharmaceutical investments and human resource development, and affect citizens' access to essential medicines.

One of the objectives of the Kenya National Pharmaceutical Policy is to promote local production and research as well as innovations in health products and technologies. The policy promotes self-sufficiency in creating high-quality health products and technologies and requires us to establish regulatory frameworks for medicines that will

be recognized by the most stringent regulatory authorities across the world. This is critical, especially in the wake of the COVID-19 pandemic, which has caused massive disruptions in the global supply of life-saving health products and technologies.

Kenya's pharmaceutical industry faces complex requirements, which include meeting product quality specifications in compliance with Good Manufacturing Practices. In order to spur sector growth, we need to establish and implement supportive legal, policy, and regulatory frameworks that promote pharmaceutical manufacturing.

This diagnostic report highlights gaps, challenges, and opportunities in the pharmaceutical sector. As such, it will form the basis for a plan of action to drive the sector's growth.

Hon. Mutahi Kagwe EGH

Cabinet Secretary
Ministry of Health

FOREWORD



Vision 2030 earmarked growth in the manufacturing sector as a priority to help Kenya become an upper middle-income economy. The sector's overall medium-term goal is to increase its contribution to the country's GDP by at least 10 percent per year.

To advance industrial growth, we are promoting the development of Small and Medium Enterprise, Industrial, and Technology Parks, also known as Industrial Manufacturing Clusters, to be placed along infrastructure corridors. These parks will be self-contained areas with high-quality infrastructure and facilities to accommodate modern industrial businesses.

In 2015, the government developed the Kenya Industrial Transformation Programme, which aims to help Kenya become a primary industrial hub in Africa. This program will accelerate industrial development by making it easier to do business; helping develop SMEs; making targeted economy-wide and sector-specific interventions; developing industrial parks to compete in global niche markets where local comparative advantages can add value; and implementing sector-specific flagship projects.

The manufacturing sector has faced recent challenges, preventing it from operating at optimal capacity and achieving its Vision 2030 targets. Pharmaceutical manufacturing is one of the key sectors of focus for the government. With over 30 pharmaceutical manufacturing plants, Kenya's pharmaceutical industry is the largest in the Common Market for the Eastern and Southern Africa region. However, insufficient drugs are manufactured in Kenya to meet domestic needs. As a result, approximately 70 percent of locally used drugs are imported. The sector also relies heavily on imported raw materials for production.

Together with the Ministry of Industrialization, Trade and Enterprise Development, and the Ministry of Health, the government of Kenya intends to assess sector constraints and introduce the legal, regulatory, institutional, and procedural changes required for growth. We believe that these changes will reduce Kenya's reliance on imported drugs, help citizens access affordable local pharmaceutical products, and improve the country's regional and global competitiveness.

Hon. Betty C. Maina EGH

Cabinet Secretary

Ministry of Industrialization, Trade and Enterprise Development

PREFACE



Health care is one of the key sectors under the Social Pillar of the Kenya Vision 2030, which aims to improve the quality of life of all Kenyans through wide-ranging social welfare projects. To help realize Vision 2030, President Uhuru Kenyatta launched the Big 4 Agenda Programme in 2017, which included Universal Health Coverage as one of its pillars. Part of the objective of universal health coverage is to ensure that all people and communities can obtain high-quality promotive, preventive, curative, rehabilitative, and palliative health services, while ensuring that the use of these services does not expose them to financial hardship.

Accessing pharmaceutical products in Kenya is a significant challenge for the government and the public, due to the high cost and variable quality of medicines on the market.

To address this challenge, the government of Kenya commissioned the Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development to conduct a detailed analysis of the pharmaceutical sector, with the support of the International Finance Corporation. The goal was to identify sector constraints and create solutions that are suitable for the Kenyan context and aligned with the country's health sector reform agenda.

As part of the process of transforming Kenya into an industrializing, upper middle-income country, the government intends to promote local pharmaceutical manufacturing. It will do so by addressing sector constraints through legislative, policy, and institutional measures, enabling Kenya to become a regional leader in pharmaceutical manufacturing and an example of global best practice.

We believe that reform in the pharmaceutical sector, and specifically in pharmaceutical manufacturing, has the power to change the lives of millions of Kenyans and strengthen our relationship with our regional partners, as it will improve access to high-quality, affordable medicines.

Dr. Rashid Abdi Aman
Chief Administrative Secretary
Ministry of Health

PREFACE



The pharmaceutical sector plays a crucial role in contributing to the delivery of universal health care in Kenya. Increased local production of pharmaceutical products promises to ensure the country has a sustainable supply of essential medicines, particularly when global supply chains are disrupted.

It is essential to support the sector so that skills and capacity can be developed and the sector can become more competitive. Institutions such as the Kenya Medical Research Institute have an important role to play in promoting research to support innovation in the industry. Academia, industry, and policymakers need to collaborate in adjusting education curricula so that they address the industry's rapidly evolving needs.

Kenya leads other East African Community partner states in the number of pharmaceutical firms it has, including firms that have made great progress in certifying and implementing Good Manufacturing Practices (GMP). The sector requires continued support from government and development partners in GMP certification and implementation in order to become internationally recognized.

The government is determined to support the local pharmaceutical industry by increasingly procuring locally manufactured products, and the Kenya Medical Supplies Authority must lead the way as the authority on procurement of medicine and related products.

At the regional level, the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027 is being implemented to guide partner states in building an efficient and effective regional pharmaceutical industry that can supply national, regional, and international markets with

efficacious and quality medicines. This plan must be well synchronized with national initiatives to support the pharmaceutical sector.

This diagnostic report highlights the issues that need to be addressed to spur growth and competitiveness in Kenya's pharmaceutical sector. Implementing the report's recommendations requires our strengthened partnership and collaboration.

Working together, the Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development can help create a conducive environment for the local pharmaceutical industry to thrive. Together, we can attract greater investment into Kenya's pharmaceutical industry for the good of the country, the region, and the continent.

Lawrence Karanja

Chief Administrative Secretary

Ministry of Industrialization, Trade and Enterprise Development

\$	United States dollar
API	Active pharmaceutical ingredient
ATC	Anatomical Therapeutic Classification
COMESA	Common Market for Eastern and Southern Africa
COVID-19	Coronavirus disease 2019
EAC	East African Community
EML	Essential medicines list
EPZ	Export processing zone
EPZA	Export Processing Zone Authority
FBO	Faith-based organization
GDP	Gross domestic product
GMP	Good manufacturing practices
GOK	Government of Kenya
HR	Human resources
IMF	International Monetary Fund
IP	Intellectual property
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
kWh	Kilowatt hour
MEDS	Mission for Essential Drugs and Supplies
NGO	Nongovernmental organization
NHIF	National Hospital Insurance Fund
NQCL	National Quality Control Laboratory
PPB	Pharmacy and Poisons Board
SEZ	Special economic zone
USAID	United States Agency for International Development
VAT	Value-added tax
WHO	World Health Organization

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EXECUTIVE SUMMARY

The Kenya Constitution, 2010, gives every citizen the right to the highest attainable standard of health and wellness. Every year, the government of Kenya commits enormous resources to improve its citizens' access to quality health services. Kenya aspires to be a healthy, productive, and globally competitive nation. The government can achieve this goal by building a progressive, responsive, and sustainable health-care system to respond to routine needs and emergencies.

The COVID-19 pandemic is one such emergency where access to quality health care is critical. Having emerged in China in December 2019, by the end of April 2020 the pandemic had left hundreds of thousands around the globe dead and millions with ill health, and resulted in staggering economic devastation.

Kenya's Vision 2030 and the Big 4 Agenda Programme launched in 2018 made clear Kenya's intent to have healthy citizens, to provide opportunities for education and employment for the millions joining the labor market annually, and to become an industrialized nation by 2030. These two policy documents brought into focus the need for the Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development to work together with other stakeholders to ensure the country builds a competitive local pharmaceutical manufacturing sector. Doing so will create employment opportunities and improve access to quality medicines for Kenya's citizens.

Kenya has sufficient laws and policies to become a competitive pharmaceutical manufacturing hub in the region. Many new laws have been enacted and many others have been reviewed to create an enabling environment for businesses (both in general and pharmaceutical manufacturing) to establish themselves and thrive. Several of these laws and policies relate to the health sector function and practice, including the pharmaceutical industry, tax incentives, public procurement-related incentives, lower electricity tariffs, protection of intellectual property (IP) and IP rights, anticounterfeit goods, ethics and anticorruption practices, environmental protection, and land use.

Kenya requires a coordinated approach and system to support the effective implementation of these laws and policies, and regularly evaluate the performance of public and private sector role players in the pharmaceutical industry value chain. Robust governance and timely sharing of reports with relevant agencies in government and with policymakers for

further action will help ensure policies are implemented. This is particularly important, as many of these laws and policies either fall within the mandate of different government ministries or are contradictory, and when implemented by individual government ministries, result in process-related tensions and delays in achieving desired outcomes.

The Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development are the two key ministries that are collaborating to realize Kenya's goal of becoming a regional hub for the manufacturing and distribution of pharmaceutical products. This partnership should be complemented by other ministries and agencies working to address issues relating to corrupt practices, unreliable utilities (water and electricity from the national grid) for industry, lack of certain specialized skills in the local workforce for pharmaceutical product development and manufacturing processes, and unnecessary complexity in tax regimens.

A comparative survey was conducted of nine pharmaceutical manufacturing companies to highlight the key attributes for attracting investment in Kenya's pharmaceutical industry. The aim was to identify and map the important factors or conditions that confer an advantage on countries and pharmaceutical manufacturing companies in the fight for market share locally and globally. Of the nine companies chosen for comparison, four were from Kenya and the other five from the peer countries of Bangladesh, Egypt, Ethiopia, and South Africa.

The companies were assessed across a range of parameters. The survey found that:

- Kenya has competitive incentives for the pharmaceutical sector and a very good rating on the Ease of Doing Business index.
- Kenyan manufacturers sell less of their products locally and export more than companies in other countries.
- The cost of utilities (water and electricity) and packaging materials are higher in Kenya.
- Although workforce costs in Kenya are lower, Kenyan firms (due to lack of capacity) rely on expatriates, which results in increased workforce expenses.
- The average revenue per local manufacturing company in Kenya is low compared to that in other countries. This is largely due to the high cost of utilities and transport of goods and the country's dependence on imported inputs.
- The Kenyan pharmaceutical market is dominated, in value, by foreign multinationals.

Kenya presents a big market opportunity for locally manufactured pharmaceutical products. The country's trade treaties allow manufacturers to access other countries in the region. However, to drive and sustain the growth of the local pharmaceutical industry, these markets will need to be further developed.

Recommendations

Based on analysis of Kenya's pharmaceutical sector, the following recommendations are presented for policy consideration.

Develop a national 10-year strategic plan for the development of the pharmaceutical sector

Based on the work done in the EAC Regional Pharmaceutical Plan of Action 2017–2027, Kenya needs to develop and implement a national 10-year strategic plan to transform the pharmaceutical sector by 2030 into a competitive regional hub for manufacturing pharmaceutical products, including drug formulations for noncommunicable diseases, active pharmaceutical ingredients (APIs), excipients, and veterinary medicines.

Political ownership and support

Political leadership and support are needed to ensure that local pharmaceutical manufacturing issues remain on the agenda at the highest level in government. This will help inspire stakeholders to take necessary actions. It is necessary to:

- Strengthen the pharmaceutical sector agenda and representation in the National Investment Council, particularly in order to prompt government engagement with the private sector in pharmaceutical manufacturing and associated clusters.
- Include the performance metrics of the pharmaceutical industry (manufacturing and the entire value chain) so that performance can be monitored and reported to the relevant House and Senate Committees under the Big 4 Agenda in the National Investment Council.

Legal landscape

There are many complementary laws aimed at spurring the local manufacturing industry (including the pharmaceutical sector) and the distribution of its products in Kenya. However, these fall within the mandate of different government ministries. The following measures are therefore necessary:

- A multisectoral committee needs to be created to own and facilitate the review and implementation of laws targeting Kenya's manufacturing industry (especially for health products).
- A clear timeline (possibly every five years) needs to be set for reviewing and reporting on the prevailing environment in Kenya (and regional markets). Laws in force to encourage local manufacturing need to be reviewed to ensure they remain appropriate and relevant.
- The government of Kenya needs to monitor and advocate for laws and policies in the East African Community (EAC) and Common Market for Eastern and Southern Africa (COMESA) trading blocs that do not restrict its exports.
- Investment laws in Kenya need to be harmonized and Kenya needs to position itself to benefit from the African Continental Free Trade Area and other priority regional economic communities.

Regulatory landscape

Multiple regulatory bodies govern function and practice in the pharmaceutical sector. Some fall within the sector and Ministry of Health, while others are with other government ministries. There is, therefore, a need to:

- Develop an Inclusive Coordination Framework that ensures a more harmonized approach in the regulation of the pharmaceutical industry and adequate involvement and representation of the sector.
- Implement the existing regulatory policies, and measure and report on performance to the relevant Senate and House subcommittees via the National Investment Council, including on the regulation of the manufacturing and retail pharmacies subsectors.
- Clarify the roles and responsibilities of the National Quality Control Laboratory (NQCL) and the Pharmacy and Poisons Board (PPB). Although the law clearly states their respective responsibilities, there is a perceived conflict between the two entities. Their responsibilities must be clarified to increase collaboration and ensure they can perform their mandates effectively.
- Undertake a workload assessment to ensure enough resources are provided to the PPB and the NQCL so that they can perform their roles effectively.
- Conduct a nation-wide assessment of pharmacy outlets to identify unregistered pharmacies and take corrective actions.
- Design policies to incentivize and support manufacturers achieving World Health Organization (WHO) prequalification or similar quality assurance compliance.

EXECUTIVE SUMMARY

- Advocate for accelerated adoption of cross-recognition of common pharmaceutical regulatory standards and practices in the EAC and COMESA regions to create an enabling environment for Kenya's exports.

Human resources

There are skill gaps in Kenya's workforce. From the project research, it was observed that the industry finds that pharmacy courses provided by local universities are too theoretical and do not impart the practical knowledge required in manufacturing. There is also a lack of specialized engineering skills to provide ancillary support services to pharmaceutical manufacturing. In order to tap the full potential of Kenya's human capital for pharmaceutical manufacturing:

- Policymakers and education specialists need to adjust the current education curricula to ensure that skills in the workforce are adapted to industry needs. Curricula should be based on competencies required and should focus on acquisition of skills.
- Metrics need to be developed to measure outputs and outcomes of internships and on-the-job training. This will help incentivize the private sector to invest in training and mentorship programs for secondary and tertiary levels of education to nurture talent that can drive innovation.

Operational landscape

Certain operational challenges affect domestic pharmaceutical manufacturing, such as reliable electricity and water supply, bureaucratic processes, access to funds, and reliance on imported raw materials. For Kenya to become a hub for pharmaceutical manufacturing and a major exporter of pharmaceutical products to the rest of Africa, the following actions need to be taken:

- Local pharmaceutical manufacturers need to increase the efficiency and effectiveness of their operating models, re-engineer their operations, and take advantage of the current structural, tax, and financial reforms implemented by the government of Kenya. Adoption of technology and turnkey enterprise resource planning should be a required business standard for local pharmaceutical manufacturing firms as this will go a long way toward improving operational efficiency, reducing waste, and ensuring that products meet the highest quality standards.
- The Kenyan government should continue to ensure that the macroeconomic environment is conducive for business. It can do so by implementing responsive policies and improving standards of service within government

institutions. Blockchain and artificial intelligence-based solutions for the industry could also be explored to increase transparency and accountability internally for strategic business units and externally for role players in the value chain, including the supply chain.

- Provide the pharmaceutical manufacturing industry with the required industrial infrastructure, such as a low-cost, reliable, and quality supply of electricity and water and waste management facilities such as eco-friendly Common Effluent Treatment Plants. This could be facilitated by making available common user facilities in SEZs/EPZs and industrial parks.
- Ensure local low-cost quality inputs are available for manufacturing pharmaceutical products. Companies with credible capacity can be encouraged, through tax incentives and limited-period sovereign guarantees to credit, to access requisite technology for the production of active pharmaceutical ingredients (APIs) and excipients (inactive ingredients for stabilizing a drug, bulking it up, or enhancing its therapeutic effectiveness).
- Encourage pharmaceutical manufacturers to invest in strategic purchasing through integration into local trade networks that allow them to have negotiating power, both locally and internationally.

Research and development

Currently, the maturity level of pharmaceutical manufacturing is Level 1. The pharmaceutical industry will need to improve its maturity level and move to complex and high value-added production to reduce its reliance on imports. Research and development of new products in Kenya requires the combined effort of many stakeholders in the industry. It is especially important to ensure that:

- Both operational and scientific research is implemented by pharmaceutical manufacturers in partnership with academia, research institutions, and policymakers. This will provide much-needed evidence for strategic decisions on and investments in processes and products.
- Adequate research funds are made available from a national pool by both the public and private sector to reduce the limitations that hold back research work to find and develop new drugs and technologies in support of the local industry.

Improving access to local and regional markets

The Kenya Export Promotion and Branding Agency (BrandKE) is mandated to promote Kenya's exports of goods and services and coordinate related activities. It

needs to address policy issues with trade partners, address bottlenecks, provide a platform for and actively promote Kenyan pharmaceutical products, and expand access to markets for Kenyan pharmaceutical manufacturers.

- To promote Kenyan products, the government of Kenya needs to use its embassies and trade missions to work with BrandKE.
- To increase domestic demand for locally manufactured pharmaceutical products, strategic partnerships need to be created with health-care providers – including hospitals, health-care franchises, and pharmacies – especially in the current environment, which is focused on the Sustainable Development Goals and universal health care. Pharmaceutical manufacturers should leverage the Buy Kenya Build Kenya strategy (especially the preferential public procurement policy for locally produced pharmaceutical products) to increase local brand recognition and loyalty.
- To assure the quality of products and grow the market for exports, pharmaceutical manufacturers in Kenya should invest in good manufacturing practices (GMP).

Improving Kenya's place as an investment destination

Globalization has increased competition among countries as sources for goods and services, low-cost and skilled labor, and capital. For Kenya to become more competitive as a destination for setting up pharmaceutical manufacturing industries:

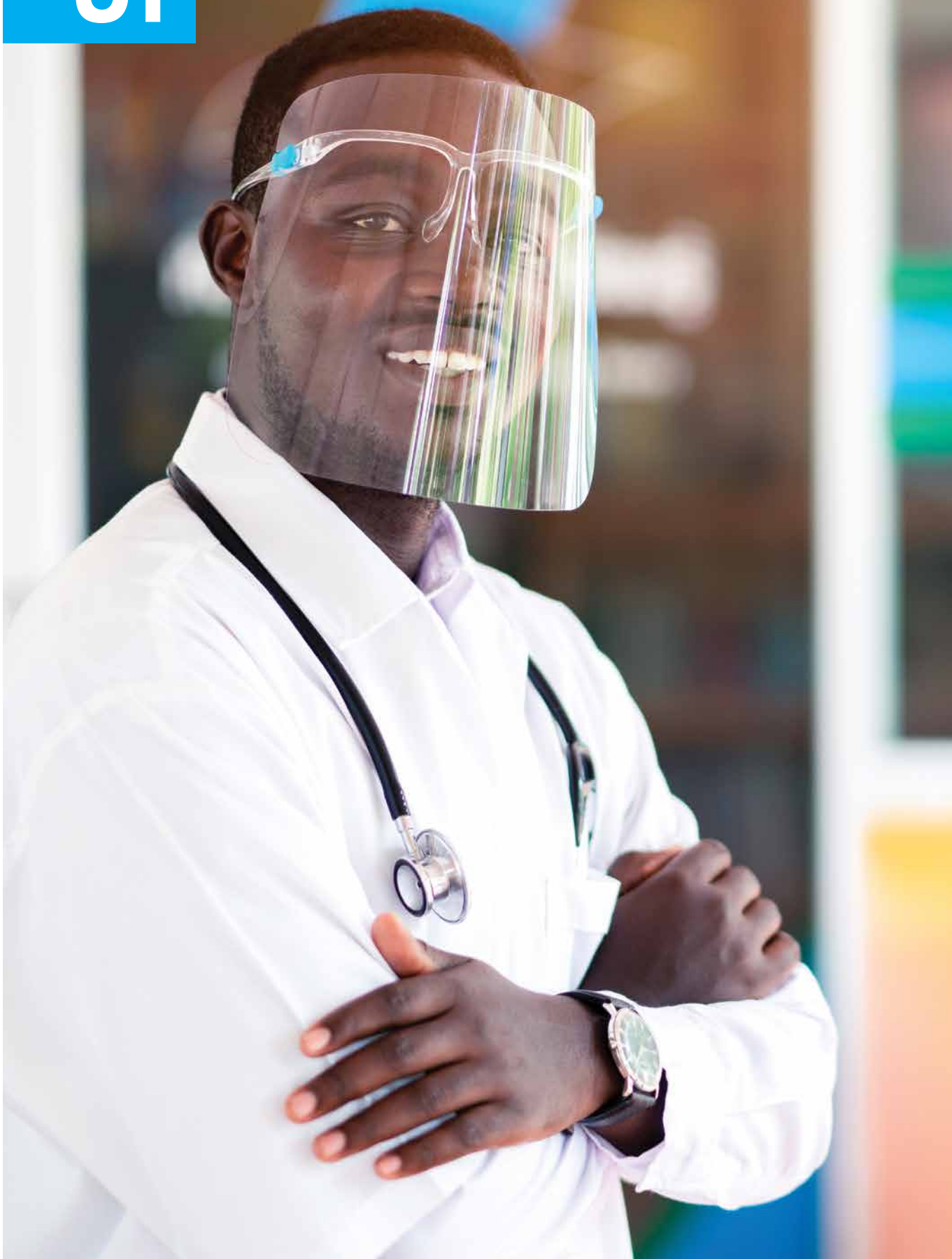
- A comparative analysis needs to be done, every five years, of Kenya's competitive advantages against those of its peers. The findings should be used to inform sector policy, strategies, and packaging of the country as a preferred investment destination for pharmaceutical manufacturing.
- A national 10-year pharmaceutical sector strategic plan and policy need to be developed. These will help Kenya create the conditions to become a competitive investment location for the manufacturing and export of pharmaceutical products.

These recommendations need to be fully implemented for Kenya to become a regional pharmaceutical manufacturing hub by 2030. The goal is for Kenya to:

1. Reduce its current total dependence on imported APIs and excipients to 50 percent and grow its local capacity to produce more.

2. Increase the proportion of pharmaceutical manufacturers that meet national GMP standards from 65 percent to 100 percent, and support those manufacturers in the country that fully comply with global GMP requirements.
3. Increase the proportion of national pharmaceutical products demand met by locally manufactured products from the current 30 percent to about 65 percent.
4. Eliminate unregistered retail pharmacies in the country to minimize the risk of substandard products entering the supply chain.
5. Increase its market share from \$63 million annually in pharmaceutical exports to COMESA, the EAC, and the rest of Africa to \$678 million (which translates to a 5 percent share of the \$13.6 billion market for pharmaceutical products in Africa).

01



Introduction

1.1 Global and regional overview

The health and well-being of citizens is essential for a country's social and economic development. The health-care sector is a key contributor to economies nationally and globally. According to WHO estimates, between 2000 and 2017, global health spending increased by 3.9 percent per year: 6.3 percent per year in middle-income countries and 7.8 percent per year in low-income countries.¹ The per capita health expenditure across countries' and regions' economies varies significantly, with \$5,252 in high-income countries, \$491 in upper-middle-income countries, \$81 in lower-middle-income countries, and \$40 in low-income countries.² The global per capita health expenditure is expected to double by 2050, but with disparities between countries. In this period, it is expected that lower-middle-income countries will see the fastest annual growth of 2.64 percent, as their governments increase investment in the health sector and economic development to meet the needs of their growing populations.

1.1.1 Access to medicines remains a focus area

Access to medicines remains a high priority for the global health community. Today, an estimated 2 billion people do not have access to medicines. Most of them live in low-income and middle-income countries.³ WHO has addressed the multidimensional nature of improving access to health products in its draft Roadmap for Access 2019–2023, which outlines 10 priority areas, including fair pricing, management of intellectual property, procurement, and supply chain management. WHO's 2019 global health spending report highlights how most countries that experienced high rates of economic growth moved towards increasing spending on health, but the transition from aid has been slower.⁴ This health financing transition has been accompanied by increased resource pooling and public financing.

1.1.2 Global pharmaceutical market driven by the United States and pharmerging countries

Global spending on medicines and medical supplies is estimated to be 19 percent of global health-care spending, which was \$1.5 trillion in 2016.⁵ A number of factors have contributed to the growth of the industry, including scientific and technological advances, sociodemographic changes, increasing demand for medicines, and the liberalization of trade. The critical growth drivers of the market will continue to be the United States and

pharmerging markets,⁶ which are expected to experience between 4 percent and 7 percent and between 5 percent and 8 percent compound annual growth, respectively. In the top five European markets, spending on medicine and medical supplies will grow between 1 percent and 4 percent between 2018 and 2023, compared to growth of 3.8 percent between 2014 and 2018. China is the largest pharmerging market, and its pharmaceutical market is expected to be worth between \$140 billion and \$170 billion by 2023. All pharmerging markets will see slower growth in the next five years than in the past five as the economic growth and health-care access expansions of the past contribute less to growth.⁷

1.1.3 Global investment trends in the pharmaceutical sector

Pharmaceutical companies are continually looking to acquire new technology, intellectual property, and drugs. Most mergers and acquisitions in the industry are undertaken with a view to boost product portfolios and expand market reach with products and services. In 2019, most of the deals in the pharmaceutical life sciences industry were in the United States market, where they totaled \$233.9 billion (65 percent of the global total in value), followed by Western Europe at \$105.7 billion (30 percent). The value of the deals made in Asia Pacific and the rest of the world was notably lower in 2019, accounting for 5 percent of the global total.⁸

In 2019, the pharmaceutical and life sciences industry witnessed 248 merger and acquisition deals, with an equivalent number in 2018. However, the total value of these deals in 2019 was \$358 billion, a 62 percent increase from 2018. This rise in value was mainly due to 12 megadeals (a megadeal is one in which the target company is more than \$1 billion in value). The two biggest deals of 2019 were the acquisition of Celgene by Bristol Myers Squibb at a cost of \$99 billion and the Allergan acquisition deal by AbbVie Inc. at a cost of \$86.5 billion.

In the United States, investors continued to show increased interest in novel and originator pharmaceuticals, which have historically enjoyed strong price positions and margins. In Europe, investors remained focused on manufacturers of mature branded and generic medicines.

The following emerging global trends are worth noting:

Changing customer expectations

Customers are examining the value of medicines more carefully, looking for value for money for new therapies that show better real-world clinical outcomes. This trend is imposing cost constraints on health-care providers.

New business models

The prevailing management culture, mental models, and strategies upon which the pharmaceutical industry relies will need to change in order to remain relevant in a world where ways of doing business are rapidly changing.

Chronic diseases

The global market for chronic disease management is expected to register a compound annual growth rate of over 14 percent for the next five years. Chronic disease product pricing and access models will require continuous innovation. An industry-led initiative to reduce the price of medicines for noncommunicable diseases has not translated into improved access to these products.

Primary health care

To achieve universal health care, many markets are investing more in primary care, with more prescription products switching to over-the-counter status and services to auxiliary care or self-care.

Risk-averse regulatory system

Due to high caution in the approval of new medicines, only 11 percent of the molecules that enter pre-clinical development reach the market. The research and development process is estimated to cost \$1.18 billion per drug and there is no guarantee of a good return on investment. There is a \$30 billion gap between the projected profits from new drug launches and the drug spending of public health programs in developed countries.⁹

Quality of products

According to research, 12.4 percent of antibiotics and 19.1 percent of antimalarials in low- and middle-income countries are substandard or falsified. The negative economic impact is estimated to be between \$10 billion and \$200 billion. In Sub-Saharan Africa, about 16.3 percent of 1,530 randomly sampled cardiovascular medications (anticoagulants, antihypertensives, and statins) failed active pharmaceutical ingredient content analysis.¹⁰

1.2 The African pharmaceutical market

1.2.1 Economic status

In 2019, Africa's population was estimated to be 1.31 billion. This number is expected to double by 2050.¹¹ In 2018, about 429.1 million people in Africa were categorized as extremely poor. Average economic growth of 5 percent a year is needed for the next 10 to 15 years to eradicate poverty on the continent.¹² According to the African

Development Bank, economic growth in Africa was about 3.4 percent in 2019.¹³ This was below the 5 percent growth the region realized for many years. The main reason for this was the poor economic performance of Africa's five largest economies: Algeria, Egypt, Morocco, Nigeria, and South Africa.

In the first quarter of 2020, prior to the COVID-19 pandemic, economic growth in Africa was projected to be 3.9 percent in 2020 and 4.1 percent in 2021. However, in June 2020, the African Development Bank projected that the global economy would contract by 3.4 percent in 2020 if the pandemic extends beyond the second half of 2020. Several agencies are predicting contraction in 2020, indicating the region's first recession in 25 years.¹⁴ In May 2020, the International Monetary Fund (IMF) projected the world economy will contract by 3 percent in 2020,¹⁵ while the United Nations World Economic Situation and Prospects mid-2020 report projects a contraction of 3.2 percent.¹⁶

The annual growth in global trade volumes shrunk from 4.6 percent in 2017 to 2.6 percent in 2019. This decline, which is especially high for major export commodities, includes metals and food. Inflation remains high,¹⁷ although the average inflation rate marginally decreased from 11.2 percent in 2018 to 9.2 percent in 2019. Most countries have responded by adjusting interest rates to manage domestic demand and encourage investment. The weighted average deficit-to-GDP ratio in Africa declined from 5.9 percent in 2017 to 4.8 percent in 2019 due to a stabilization in commodity prices and higher revenues for large natural resource exporters. The revenue-to-GDP ratio rose by 0.3 percentage points on average.

The manufacturing of medicines locally has been identified as an opportunity to spur growth by contributing to the diversification of the economic base away from primary commodities.¹⁸

Despite global challenges and poorer-than-expected performance, the African economy is bound to strengthen and stabilize further as continental trade barriers are more rapidly simplified in future. Furthermore, with the adoption of the Continental Free Trade Area, it is predicted that intra-Africa trade will increase, resulting in a decline in imports of over \$10 billion per year from 2022.¹⁹ In many African countries, efforts are being made to reduce their dependency on imports and to promote self-reliance. As demographics evolve and infrastructure improves, there is an increasing need for African governments to invest in health care.

1.2.2 Health-care expenditure

Public spending on health is growing in Africa and is associated with improving financial status. An increasing number of countries have in place legislative and legal



The manufacturing of medicines locally has been identified as an opportunity to spur growth by contributing to the diversification of the economic base away from primary commodities.

frameworks for universal health coverage. According to WHO, countries can scale up primary health care using domestic resources such as increasing public spending on health or reallocating spending to public health. Allocating or reallocating at least an additional 1 percent of GDP for public health care is an attainable goal in all countries today.²⁰ Efficient health systems eliminate barriers to access to quality, safe, effective, affordable, and essential health services and medicines; reduce out-of-pocket expenditures; and ensure financial risk protection for all, particularly the vulnerable and marginalized in society.

1.2.3 Overview of the African pharmaceutical market

The estimated value of Africa's pharmaceutical market was \$20 billion in 2018. With sustained investment, it is expected to be valued at \$26 billion by 2022. This will correspond to about 2 percent of the global pharmaceutical market (projected at \$1.44 trillion) in 2022.²¹ There are about 375 pharmaceutical manufacturers on the continent, with

most based in North Africa, catering to the needs of about 1.3 billion people. Those in Sub-Saharan Africa are located mainly in about nine of 46 countries, and most have small operations that do not meet international standards. By comparison, China and India, each with a similar population to Africa's, have as many as 5,000 and 10,500 manufacturers, respectively.²²

African pharmaceutical industry at an early stage of development

In Sub-Saharan Africa, only Kenya, Nigeria, and South Africa have a sizable pharmaceutical industry presence, producing to serve the local demand and export to other African countries. The companies in the region are primarily drug manufacturers that buy active pharmaceutical ingredients (APIs) from other manufacturers abroad and formulate them into finished products ready for the market. Only three companies (two in South Africa and one in Ghana) produce APIs. In general, the requisite chemical industry to support production of APIs is missing.²³

Regulatory standards and their enforcement across Sub-Saharan Africa lag behind global standards. As the region develops a local pharmaceutical industry, greater attention needs to be paid to adopting global standards and/or establishing, maintaining, and enforcing quality standards. Governments in the region have stepped up the fight against counterfeit, expired, and substandard drugs.

Key drivers for increased consumption

The following factors have been identified as key drivers of increased consumption of health-care products and have inspired a renewed focus on achieving universal health coverage across many African nations:

■ *Changing disease burden*

Africa is experiencing an increasing incidence of noncommunicable diseases. Since 2000, cases of malignant neoplasm and cardiovascular disease have increased by 2 percent per year. In contrast, infectious and parasitic diseases have declined by about 3 percent over the same period. Over the last three years, the antihypertensive market in Kenya grew by 23 percent, compared to antibacterial market growth of 11 percent.

■ *Maturing business environment*

On business environment measures such as the Ease of Doing Business index and the Corruption Perception Index, Africa lags behind developed markets (such as the European Union and North America) and developing markets (such as Brazil and South Africa). However, trade policies such as the Continental Free Trade Agreement and the African Medicine Regulatory Harmonization efforts under implementation will contribute to a more market-friendly environment and accelerate access to medicines across the continent.

In the World Bank's Doing Business 2020 Report, Kenya was ranked 56 out of 190 countries, an improvement by five places from the previous year. Among African countries, Kenya was ranked fourth, after Mauritius, Rwanda, and Morocco. In 2019, Kenya implemented reforms including embracing digitalization, simplifying property registration processes, improving access to credit, and strengthening minority investor protection. In the World Economic Forum's Global Competitiveness Report 2019, Kenya was ranked ninety-fifth and improved its score by 0.5 points. Kenya performed well in areas such as corporate governance, future orientation of government, and business dynamism.

■ *Policy interventions to promote local manufacturing and generic drugs usage*

To effectively meet the demand for quality and affordable medicines in Africa, governments across the continent are implementing policies to boost local manufacturing capacity, with varying levels of success. For instance, in

2008, Algeria banned the import of pharmaceuticals that were being manufactured by at least three manufacturers locally and meeting market demand. The ban list included 358 pharmaceutical products of all categories. Since then, the government has modified the list several times. The Algerian government also provides pharmaceutical manufacturers with access to purpose-built industrial parks. In Morocco, the government introduced an "equivalent price" mechanism, with periodic reviews of drug prices, to promote generic drug use. These policies are yielding results: eight of the top 20 and three of the top 10 pharmaceutical manufacturers in Africa are local or regional players producing branded or unbranded generic medicines for consumption on the continent. Furthermore, 57 percent of drugs (by volume) consumed in the first quarter of 2018 were generics.

■ *Partnerships with government bodies*

The leading companies with interests in Africa are partnering with government bodies to increase awareness about disease and treatment, and to provide affordable medicines. In 2018, approximately 300 public-private partnership programs were implemented in Africa, about 40 of which focused on noncommunicable diseases. The nature of these programs ranges from treatment availability and financing to health system infrastructure development and system strengthening. These activities are components of crucial access strategies employed by pharmaceutical companies and are required for effective local operations across the continent.

■ *Digital innovations*

The rapid growth in digitalization in all countries on the continent presents new opportunities to improve health-care delivery to the most vulnerable and those in hard-to-reach areas. High penetration of mobile subscriptions allows digital innovations to scale up in Africa. For example, according to the Communications Authority of Kenya, mobile penetration was estimated to be 112 percent in December 2019. The penetration of 2G and 3G networks was estimated to be 96 percent and 93 percent, respectively.²⁴

Several initiatives have been implemented to increase awareness of disease and provide telemedicine platforms, inventory management, disease monitoring, and health-care financing. In Kenya, some notable examples of innovation include:

■ *Weltel*: An SMS-based messaging service to monitor and support antiretroviral therapy. It also supports increased adherence to treatment regimens.²⁵

■ *Child Count+*: A patient-tracking application that collects information about pregnant women and children under 5 years and prioritizes community health worker visits.

- **M-Tiba:** Based on Safaricom’s (a mobile network operator) M-Pesa platform, the app allows users to send, receive, and save funds for medical access. M-Tiba has also partnered with the National Hospital Insurance Fund (NHIF) to provide health-care insurance to 2,000 households. The app has over 1 million users.²⁶

1.2.4 Investments in pharmaceuticals in Africa

In the last 10 years, the African pharmaceutical industry has benefited greatly from private sector investments. According to McKinsey Healthcare, approximately 85 percent of the African pharmaceutical market is in the top 15 countries.

Furthermore, there is documented interest by international investors. For instance, IFC’s first pharmaceutical manufacturing deal in the region outside of South Africa is the \$25 million project with Universal Corporation Limited (UCL) based in Kikuyu town in Kenya. In 2018, there was also an investment by IFC in Goodlife in Kenya and LeapFrog in Tanzania.

1.3 The East African Community: Regional context and health industry

The East African Community (EAC) is a regional intergovernmental organization of six partner states, namely Burundi, Kenya, Rwanda, South Sudan, Tanzania, and Uganda. Its headquarters are in Arusha, Tanzania. The EAC is home to 177 million citizens, of which over 22 percent live in urban settlements. The EAC’s GDP is \$193 billion.²⁷

1.3.1 Investments and reforms in the EAC to improve business environment

The EAC partner states are continually seeking to improve the business environment to grow existing businesses and attract new investments into various economic sectors. The states have undertaken initiatives to increase cross-border trade through automation and upgrades to information and communications technology such as electronic data interchange systems. According to a survey conducted by Uganda Revenue Authority and Rwanda Revenue Authority, in the Northern Corridor these reforms have reduced the number of days required to transport cargo from Mombasa to Kampala from 18 to four days, while the transit time from Mombasa to Kigali has been reduced from 21 to five days.²⁸

As per the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, EAC partner states have also made considerable investments to upgrade the ports and railway systems. Kenya and Tanzania are making large-scale investments in new berths and facility upgrades at the ports of Mombasa and Dar es Salaam, respectively, to improve efficiency and competitiveness. The East African countries are also modernizing their railway systems, with standard-gauge railway construction under way in both the Northern and Central corridors. All of these investments, as well as reforms on the ease of doing business and the deepening of the regional integration process, are expected to make the region more attractive to investors and encourage intra-country trade.

TABLE 1: PHARMACEUTICAL INVESTMENTS IN AFRICA, 2014–2020

Key Investments in Pharmaceuticals in Africa (2014-20)		
2019	Kilitch Drugs (in manufacturing plant)	Ethiopia
2019	TLG in Cipla’s distribution and marketing business	French West Africa
2019	Africure in manufacturing plant	Zimbabwe
2018	Cipla in Mirren	South Africa
2018	Carlisle Group in Abacus	Uganda
2016	Strides Shasun in UCL	Kenya
2016	Catalyst in Zenufa labs	Tanzania
2016	Actis in Medis Group	Tunisia
2016	LeapFrog in Good Life	East Africa
2016	LeapFrog in Pyramid Group	Tanzania
2015	Synergy Managers in Curist	Ghana
2014	Caurius Management in CIPHARM	Côte d’Ivoire



Trends in the EAC that are reshaping the pharmaceutical market include increasing political support for local pharmaceutical manufacturing and shifting health-care policies and practices that favor generics and biosimilar products over patented medicines.

1.3.2 Interest among EAC partner states in promoting the pharmaceutical industry

In fulfillment of the 2nd Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, there is increasing interest among EAC partner states in improving their pharmaceutical industries. Several countries have developed a strategic plan for their pharmaceutical industry. Examples include the Kenya Good Manufacturing Practices Roadmap, the Strategy for Promotion of Domestic Pharmaceutical Production in Tanzania (2013–2023), and Uganda’s National Pharmaceutical Sector Strategic Plan (2015–2020).

1.3.3 Health-care financing

General government health expenditure comprises more than half of total health spending in all EAC countries, with a high share of external resources, especially in Burundi

(50 percent of total health expenditure). Donor funding accounts for a significant proportion of the financing for the procurement of medicines, particularly for priority endemic diseases such as HIV, TB, and malaria. Private health expenditure (as a percentage of total health expenditure) ranges from 39 percent in Burundi to 75 percent in Uganda.

The EAC countries could improve access to health care through social health protection programs. On average, only 25 percent of the EAC population is covered by some kind of social health protection mechanism. Coverage varies from less than 1 percent in Uganda to 95 percent in Rwanda, where coverage is considered effective and approaching sustainability. The combination of economic strength and an expanding middle class is driving demand for medicines across East Africa.

1.3.4 East African pharmaceutical sector still at low maturity

Trends in the EAC that are reshaping the pharmaceutical market include increasing political support for local pharmaceutical manufacturing and shifting health-care policies and practices that favor generics and biosimilar products over patented medicines. According to the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017–2027, identified challenges in the pharmaceutical industry in emerging markets, even in the EAC region, include scarcity of funding, infrastructure gaps, shortage of highly skilled health-care professionals, and absence of local market data.

Frameworks that describe pharmaceutical value creation include five levels based on sophistication. These levels range from Level 1, which is basic and defined by the import of finished pharmaceutical products, to Level 5, which indicates a more sophisticated, research-based pharmaceutical industry. Higher levels indicate increasing value addition, investments, and regulatory requirements. The EAC pharmaceutical sector is predominantly at Level 1, with limited local manufacturing activities largely confined to Levels 2 and 3.²⁹

Domestic firms are primarily involved in manufacturing finished pharmaceutical products rather than manufacturing APIs. Overall, in the EAC there is little pharmaceutical research and development activity in innovator products. The production of APIs requires developing the knowledge base, acquiring technology, and scaling operations to justify such an investment.

1.3.5 Low share of domestically manufactured medicines

Locally manufactured medicines account for about 30 percent (in value) of market share in Kenya, while in Uganda and Tanzania, the share amounts to 20 percent and 12 percent, respectively. A Kenya pharmaceutical trade data report by Kenya's Pharmacy and Poisons Board (PPB) and a scoping study by the Clinton Access Initiative on the East African pharmaceutical market show that:

- Anti-infectives and immunological and cardiovascular agents make up about 50 percent of the market share by value.
- An estimated 66 percent of disease conditions are covered by locally produced medicines.

1.3.6 Innovation funds and increasing insurance coverage provides opportunities to produce APIs

The East African Health Research Commission was set up in 2015 with the mandate to promote and coordinate research and development activities in the region, including developing capacity in pharmaceutical research and development. A regional innovation fund has not been established, but each member state has set up its own national innovation fund.

Kenya, Rwanda, Tanzania, and Uganda have established such funds, with priority given to health, agriculture, and climate change. The government of Kenya has also set a target to achieve 80 percent enrollment of the population in its NHIF program by 2025. Tanzania plans to cover 50 percent of its population by the end of 2020, whereas Uganda aims to cover its entire population by 2025.³⁰ These will lead to increased demand for pharmaceuticals and may provide the required scale of operations for the API production base in Kenya.

1.4 Kenya: Country context and health industry

1.4.1 Economic status and outlook

Kenya's 2019 population and housing census put the country's population at 47,564,296, 50.5 percent which are female. A total of 35.7 million people (75.1 percent) are below 35 years, while 32.73 million (68.9 percent) live in rural areas. In urban areas, the majority of the population is between 20 and 34 years of age, with a median age of between 20 and 24 years. In contrast, in rural areas, most of the population is between 5 and 9 years of age, with a median age of 10 to 14 years. The average Kenyan has attained primary and secondary levels of education.

Kenya is one of the fastest-growing economies in Sub-Saharan Africa. In 2019, Kenya's GDP was about \$98 billion, recording real GDP growth of 5.9 percent. This growth was driven by household consumption and improved service delivery in public administration, information technology, finance and insurance, and transport and storage. The stable exchange rate in 2019 was due to the reduction of the current account deficit from 5.0 percent of GDP in 2018 to 4.9 percent in 2019. Foreign exchange reserves increased from \$9 billion in 2018 to \$9.4 billion at the end of August 2019. This increase is comparable to six months of imports, or more than the EAC convergence criterion of 4.5 months.

In 2019, the fiscal deficit was about 7.5 percent of GDP, down from 8.8 percent in 2017, due to continuing fiscal consolidation and better mobilization of domestic resources. Kenya's economic growth has resulted in a reduction of the poverty rate from 46 percent in 2005/6 to 36 percent in 2015/16, with the bottom income quintile receiving only 4 percent of income. Unemployment fell marginally from 9.5 percent in 2014 to 9.3 percent in 2018.

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The COVID-19 pandemic poses serious threats to the economy and various industries but also presents opportunities.

However, public sector debt rose to 58 percent of GDP in 2019, up from 41 percent in 2013, and became more nonconcessional (67 percent) than concessional (33 percent). The debt creates risks for refinancing, cost escalation, and foreign exchange. Due to Kenya's liquidity challenges, in 2018 the IMF raised the probability of Kenya's stress level from low to moderate.

Prior to the COVID-19 pandemic, real GDP was projected to grow by 6 percent in 2020 and 6.2 percent in 2021. However, these projections are likely to change due to COVID-19. Macroeconomic stability is expected to continue in 2020 and 2021, with inflation around 5 percent and the fiscal deficit narrowing. The positive outlook was informed by anticipated favorable weather, increased crude oil production and exports, the government's efforts to attract more direct investment, the benefits of the Continental Free Trade Agreement, and the government's commitment to the Big 4 Agenda. Manufacturing as a share of GDP has been constant at 9 percent for more than 10 years, while manufacturing value added is a dismal 5 percent of GDP. Agriculture remains the largest sector: in 2018, it accounted for 52 percent of GDP, 56 percent of employment, and 65 percent of foreign exchange earnings. The 2018/19 drought slowed economic growth and reduced food security. Investments in sectors with greater capacity to absorb labor have been low, and therefore many of those joining the labor market remain unemployed.

1.4.2 Economic effect of COVID-19 pandemic

Globally, epidemics and pandemics have caused havoc for centuries. The Spanish flu, in 1918, spread to many parts of the world and left millions of people dead. At the dawn of 2020, a new flu pandemic was rapidly spreading across the world. The disease was caused by a coronavirus and has been named COVID-19. It has caused economic devastation and thousands of deaths. Specifically, the pandemic has had unprecedented adverse effects on health systems, financial markets, and vulnerable industries such as manufacturing, tourism, hospitality, and travel.

The global economy is forecast to contract by 0.9 percent in 2020. In Kenya, GDP growth for 2020 is expected to decline significantly, with the Central Bank of Kenya estimating growth of 3.4 percent. The pandemic has compounded the economic impact of a locust invasion on the agricultural industry, increasing food insecurity. The COVID-19 pandemic poses serious threats to the economy and various industries but also presents opportunities.

These opportunities and threats are discussed below.

Threats:

Limited understanding of COVID-19 globally, the mitigation measures instituted, and prevailing uncertainty pose a real threat to Kenya's economy for years to come. This will affect the operating environment of workspaces and undermine the production of goods and services, workforce participation, and productivity. The reallocation of many resources for non-health interventions to address the COVID-19 pandemic is likely to affect many facets of the economy and result in overall poor economic performance for some time to come.

Opportunities:

According to the United Nations International Development Organization's report on world manufacturing output, despite the COVID-19 challenge, the manufacturing industry (including of pharmaceutical products) is expected to register growth of 2.1 percent in 2020. Kenya's pharmaceutical industry is also expected to have a positive growth outlook.

The COVID-19 pandemic has, however, severely impacted fair trade in medical products and especially pharmaceutical products. India, a major exporter of pharmaceutical products to Kenya, restricted the export of 26 pharmaceutical ingredients and finished products (medicines) manufactured by them. Compared to April 2019, Kenyan imports of pharmaceutical products from India fell by 42 percent in May 2020. Kenya's exports to Tanzania and Uganda in May 2020 also witnessed significant declines of 21 percent and 23 percent compared to April 2019.

To mitigate supply shortages and reduce its reliance on India and China, Kenyan pharmaceutical manufacturers need to identify and evaluate alternative sourcing partners or invest in capacity to produce these key ingredients locally. During the peak of the COVID-19 pandemic, the pharmaceutical sector witnessed a sharp increase in demand for vitamins, supplements, and minerals as consumers purchased them to boost their immune systems. Globally, the sales of specific antivirals also increased due to their off-label use in management of COVID-19 patients. Another area that witnessed a spike in sales was medical supplies such as gloves and syringes. These three areas present opportunities for Kenyan manufacturers of pharmaceutical products and medical devices.

1.5 The health sector and legal landscape

Kenya has a well-developed health sector that responds reasonably well to the country's needs. The health system is resilient and continually adapts to improve access to services for citizens. Legal, policy, and regulatory frameworks govern standards and practices in the sector. The current health sector landscape in Kenya is detailed below.

1.5.1 The health system

Health is enshrined as a right under the Kenya Constitution 2010, and the government has committed enormous resources every year to fulfill its promise to improve citizens' access to quality services. The Constitution and health sector envision a healthy, productive, and globally competitive nation through building a progressive, responsive, and sustainable health-care system for accelerated attainment of the highest standard of health for all citizens. The sector is led by the Cabinet Secretary for Health at the national level, who is responsible for health policy, health regulation, national referral health facilities, capacity building, and technical assistance to counties. The Health Sector Partnership Coordination Framework guides engagements between the Ministry of Health, county governments, and external and nonstate partners.

A resilient health system is one that continually seeks to improve the quality of its products and services and the sustainability and efficiency of commodity procurement and delivery. In general, strengthening a health system should involve developing sound legal frameworks to ensure public trust; building information systems to monitor performance, assess quality, and align incentives to outcomes; improving early-warning mechanisms for disease outbreaks and natural disasters; and developing processes for systematic reduction and containment of national and global health risks.

Since devolution in 2013, Kenya's public health sector has been run by the national government and the 47 county governments. The national government is responsible for health-care service delivery at the Level 6 national teaching and referral hospitals (Kenyatta National Hospital, Moi Teaching and Referral Hospital, National Spinal Injury Hospital, and the Mathari Teaching and Referral Hospital). The counties are responsible for providing Level 1 to Level 5 services, such as county referral, primary care, and community health.

The private sector consists of for-profit commercial players and not-for-profit players such as faith-based organizations (FBOs) and nongovernmental organizations (NGOs). The private sector dominates the nursing home segment and health clinics. The public sector and FBO/NGO sectors own most of the health centers and dispensaries in the country.

The FBOs can be divided into three categories:

- The Kenyan Conference of Catholic Bishops, which has many Catholic mission hospitals. It currently has 453 health facilities, 18 medical training colleges (nursing, pharmacy, and clinical medicine), and more than 46 community-based health programs and orphans-and-vulnerable-children programs.
- The Christian Health Association of Kenya, a protestant membership-based organization, has about 507 health facilities spread across the country.
- The Supreme Council of Kenyan Muslims is the umbrella body of all Muslim organizations, societies, and groups in Kenya. It coordinates health activities and services provided by Islamic facilities and institutions.

Increasing insurance coverage

The Kenyan government's budget allocation to health remains low at 6 percent. This is below international benchmarks as well as regional commitments, such as the 2001 Abuja Agreement, according to which governments committed to spend 15 percent of their national budgets on health. Curative services take the largest share of the budget, with limited financing targeted at preventive and promotive health. In 2015/16, the country spent 2.5 percent of pooled funds on health.

It is estimated that 17 percent of Kenya's population has access to health insurance. Insurance coverage varies by region, with higher coverage for the urban population (27 percent) than the rural population (12 percent). Health insurance coverage is positively correlated to wealth of population segment. It is higher in the richest wealth quintiles at 42 percent compared with those in the poorest quintile at 3 percent.³¹

In the 2018/19 financial year, the government allocated about 205.6 billion Kenyan shillings to cover expenditure on health services. As health is a shared function under the current Constitution, the allocation split was 97.5 billion Kenyan shillings for the national government and 108.1 billion Kenyan shillings for the 47 county governments. That budget allocation represented year-on-year growth of 57.8 percent for the national government and 28.7 percent for the county governments.

In 2017/18, NHIF membership increased by 13.2 percent to 7.7 million. The membership from the formal sector rose by 4.3 percent compared with a 23.3 percent rise in the informal sector. Receipts from members rose by 27.1 percent to 44.5 billion Kenya shillings, while payouts increased by 41.4 percent to 37.2 billion Kenyan shillings.³²

Under the Big 4 Agenda, Kenya is committed to achieving universal health coverage. To move the country towards achieving this goal, the government has increased its investment in new initiatives and is reforming the NHIF

and the governance of private insurance companies. Financing mechanisms have been introduced to reduce the burden on poor and vulnerable groups. Examples include abolishing user fees at public health facilities, free maternity services, lease of medical equipment, and the Health Insurance Subsidy Programme for the poor. The NHIF has employed mobile technology, such as USSD (unstructured supplementary service data) and apps, to increase enrollment and ease of premium payments. The NHIF has also broadened the benefits package, which now includes outpatient services, cover for chronic diseases such as cancer, diabetes, and hypertension, and increased access to small and medium-sized private sector health facilities. These expanded benefits have led to the subscription of 2 million additional members.

Increased investment in health-care infrastructure

In 2018, the number of health facilities in Kenya grew by 10 percent to 10,820, while registered health personnel increased by 6.3 percent to 175,681. The number of middle-level medical graduates from public medical training colleges increased by 21.2 percent to 10,869, while medical undergraduates and postgraduates were expected to increase by 6.0 percent to 4,470 in the 2018/19 academic year.

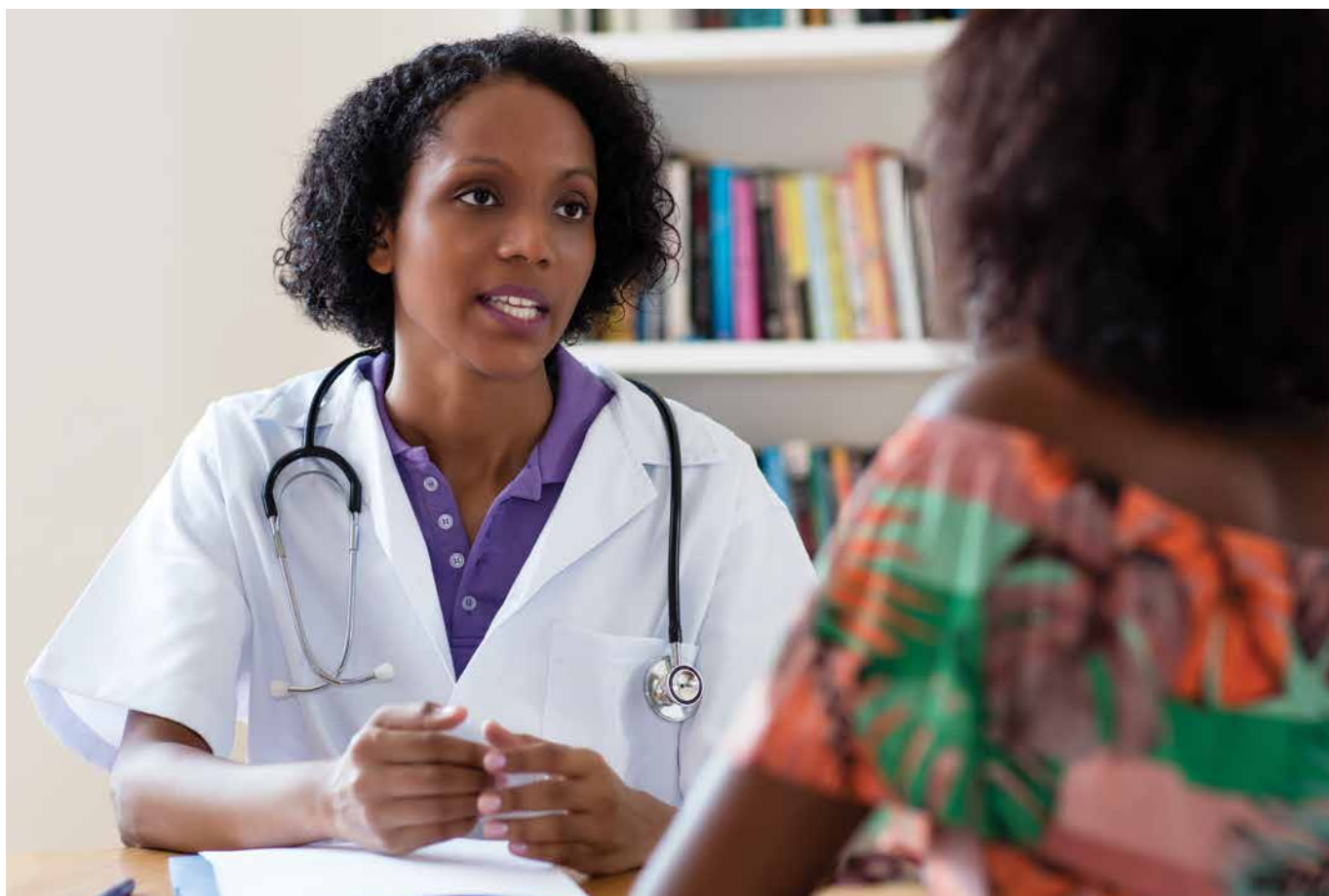
The number of registered births increased by 22.9 percent from 923,487 in 2017 to 1,135,378 in 2018.³³

Health workforce

There are eight health regulatory agencies established through acts of parliament to help govern the sector. These include:

- Nursing Council of Kenya
- Medical Practitioners and Dentist Board
- Clinical Officers Council
- Kenya Medical Laboratory Technicians and Technologists Board
- Pharmacy and Poisons Board
- Public Health Officers and Technicians Council
- Radiation Protection Board
- Kenya Nutritionists and Dieticians Institute.

Registration of health professionals across cadres has increased consistently, with the exception of pharmacists, whose numbers have varied. There is a huge disparity in health workforce distribution across the country, influenced by demographics, number of health-care facilities, and the epidemiological profile of individual counties.



According to the Kenya Health Workforce Report, 2015, 5,660 doctors and 603 dentists are currently practicing. This is equivalent to 1.5 doctors and 0.2 dentists per 10,000 people. In contrast, WHO has a recommended level of 36 doctors per 10,000 people. Currently, there are 31,896 practicing nurses in Kenya, which is equivalent to 8.3 nurses per 10,000 people. WHO's recommended ratio is 25 nurses per 10,000 people.

Kenya currently has 0.5 pharmacists and 1.2 pharmaceutical technologists per 10,000 people, which is below WHO standards.³⁴ WHO recommends that developing countries have five pharmacists per 10,000; however, 6 percent of WHO members report having less than this ratio.³⁵

Immunization in Kenya

The long-term trends in immunization in Kenya are informed by facility reports and household surveys. Kenya runs several immunization campaigns for various vaccination interventions, including vaccines against measles-rubella, polio (IPV), and human papillomavirus (HPV). In the recent past, Kenya's national vaccine and immunization programme has introduced several vaccines such as pneumococcal and rotavirus vaccines. The programme is largely dependent on development partner support, especially to improve coverage. Between 2000 and 2019, Kenya received more than \$500 million from Gavi, the vaccine alliance, for vaccine co-financing, health system strengthening, and vaccine campaigns. This support is expected to decline, with Kenya entering the accelerated phase of Gavi transition in 2022. Under this arrangement, Kenya will be expected to use its own resources to finance a higher proportion of vaccines currently funded by Gavi.

According to WHO, the cost of the routine immunization programme interventions are mainly financed by Gavi, followed by the national government. In 2014, Gavi contributed 71 percent of the total resources required to cover routine immunization, while the government contributed 24 percent and other development partners about 3 percent. The total cost of routine immunization interventions was \$75 million, with supplemental immunization activities constituting \$28 million of this amount and underused vaccines another \$25 million.

To ensure full, uninterrupted access to vaccines for its citizens after transitioning out of Gavi support, Kenya can explore the following options:

■ **Short-term strategy: Manufacturer commitments**

There are vaccine manufacturers that are committed to selling the pneumococcal, rotavirus, and HPV vaccines to countries at the same prices negotiated and accessed by Gavi-supported countries. Kenya can tap into this to help maintain low unit prices. Some of the conditions may include the need to procure through UNICEF. Some of the

preferred country price commitments are as follows:

- GlaxoSmithKline's two-dose pneumococcal vaccine price at \$3.05 for a 10-year price freeze (as of 2017).
- GlaxoSmithKline's one-dose rotavirus vaccine at €1.88 for a 10-year price freeze (based on a 2017–2021 price agreement).

■ **Long-term strategy: Technology transfer**

Kenya can explore technology transfer agreements to access vaccines. Since vaccine production is more complicated than manufacturing other pharmaceutical products, know-how is more important than intellectual property. In the past, technology transfers have led to an improvement in the accessibility and affordability of key vaccines for developing countries. For example, when the hepatitis B vaccine was introduced in industrialized countries in 1983 it cost \$100 per dose. In the late 1990s, after the technology transfer to the Republic of Korea, India, and Brazil, the price dropped to between \$5 and \$7 per dose, and this was reduced further as a consequence of financial assistance from Gavi and purchasing entities. As a result, the vaccine became more accessible and was included in most national immunization programs. India is one country that has benefitted greatly from technology transfers.

According to a WHO report, between 1988 and 2010, India received the most technologies through technology transfers. Traditionally, technologies have been transferred through bilateral agreements, joint ventures, or acquisitions. However, a new trend is the emergence of technology transfer hubs through which several manufacturers are able to receive the technology simultaneously. Examples include the NVI Influenza hub in the Netherlands in which 15 researchers/manufacturers received technology transfer, and a technology hub at the University of Lausanne in Switzerland.

According to WHO, the cost of manufacturing vaccines in Brazil, India, and China is increasing, while an increasing number of members of the Developing Countries Vaccine Manufacturers Network are ready to transfer technology, which should make the transaction cost of technology transfer lower.

For countries to successfully develop vaccine manufacturing capabilities, a well-established vaccine policy may assist in identifying when and how to consider local production.

Stakeholder landscape

There are many stakeholders in the health sector in Kenya in both the public and private space.

■ **Kenya Medical Supplies Authority**

The Kenya Medical Supplies Authority (KEMSA) is a

state-owned medical logistics service provider with the core mandate to procure, warehouse, and distribute medical commodities to the public sector. With the implementation of the KEMSA Act in 2013, the organization transitioned from a public agency to a public authority, which gave it greater autonomy. It is given priority over the private distributors when it comes to selling to public sector facilities. Both national and county-level health facilities are legally obliged to first purchase supplies from KEMSA and, only if the supplies are not available, should they then source from other (private) sector distributors.

Before devolution in 2013, KEMSA procured health commodities based on a budget it received from the National Treasury via the Ministry of Health. Today, it acts as an open market with counties procuring what they need from the supplies KEMSA buys and maintains in its warehouse. Funds for procurement are drawn from the National Treasury and development partners, and proceeds from supplies are sold to the counties. KEMSA manages the receipt of procured commodities from local and international suppliers at its warehouses in Nairobi. The commodities are then stored at KEMSA's warehouses and later distributed to over 4,000 public health facilities, some of which are very far from Nairobi. The national essential medicine list has over 600 individual items and includes generic pharmaceuticals. In 2010, KEMSA's purchases accounted for 30 percent of all prescription drugs in the Kenyan market. KEMSA's annual turnover in 2018 was estimated to be 88 billion Kenyan shillings. This includes procurement of commodities for national government, 47 counties, and public health programs supported by development partners.

Transport of commodities from KEMSA warehouses to health facilities is undertaken by private transporters on performance-based contracts. The transporters collect a proof of delivery document to verify successful and timely delivery. These are used to trigger payments to the transporters. KEMSA has eight regional depots (Eldoret, Garissa, Kakamega, Kisumu, Meru, Mombasa, Nakuru, and Nyeri). These depots are used mainly to store commodities when the warehouses in Nairobi are full or when county health facilities do not have sufficient storage space.

■ *Mission for Essential Drugs and Supplies*

The largest private sector distributor of essential drugs and medical supplies is the Mission for Essential Drugs and Supplies (MEDS). MEDS is a Christian not-for-profit organization and serves mainly FBO facilities. Previously, only FBO facilities were able to access affordable supplies from MEDS, but the organization is adapting and now supplies the county/public and commercial private sector facilities. MEDS has its own WHO pre-qualified lab to validate the quality of commodities it procures, as well as for clients in the country on contract.

■ *Development partners*

For years, Kenya has had several development partners supporting many health projects and programs. The U.S. government is by far the largest donor, through the Centers for Disease Control and Prevention and the United States Agency for International Development (USAID). The other large multilateral donors in the health sector include IFC/World Bank (Health in Africa Initiative), WHO, the Department for International Development UK, the Japan International Cooperation Agency, Gesellschaft für Internationale Zusammenarbeit (GIZ), and the Danish International Development Agency. The large development partners are united at the national level in a platform called Development Partners Health Kenya. The members come together each month to discuss pertinent issues and help avoid duplication of effort. The NGOs working in the health sector are united and coordinated via a network called Health NGOs Network Kenya.

■ *Insurance organizations*

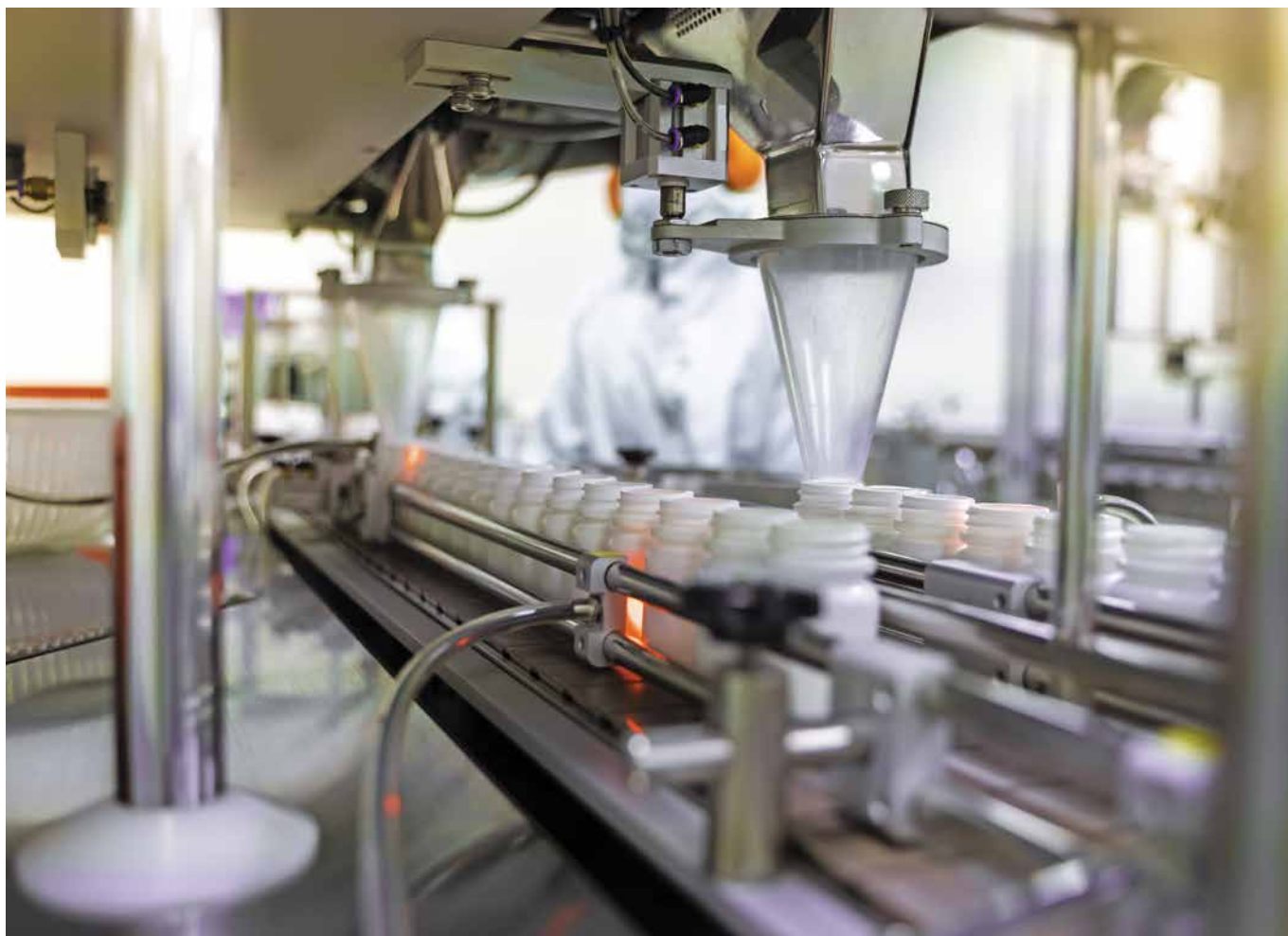
Health insurance in Kenya is provided by both public and private organizations. The NHIF is Kenya's national health insurance and has recently taken steps to expand its membership base. Membership of the NHIF is a statutory requirement for all employers and employees in the formal sector and is optional for others.

Over the past five years, via the Health Insurance Subsidy Programme and Supa Cover, efforts have been made to strengthen the membership base in the indigent and informal sectors respectively. This has borne fruit, and membership in the informal sector currently stands at 4 million, making total membership of the NHIF about 7 million people or 35 percent of the population.

Regulated by the Insurance Regulatory Authority, private insurance covers 2 percent of the population. Jubilee Insurance has the largest market share at 26 percent, followed by AAR Insurance at 17 percent and UAP at 14 percent. Microinsurance is growing and leverages the mobile money penetration in Kenya for convenient and affordable health services and medication insurance cover. Currently, about 1.5 million Kenyans are covered by private health-care insurance. In total, there are about 15 to 20 companies that provide health insurance cover.

1.5.2 Legal landscape

As noted earlier, resilient health systems constantly seek to improve the quality of products and services and the sustainability and efficiency of commodity procurement and delivery. To make such improvements, responsive national health laws and policy guidance are required. In Kenya, over the years many laws have been enacted by parliament and existing laws revised to adapt to the changing environment. These laws govern both function and practice in the health sector and help manage demand and improve access to



In many African countries, efforts are being made to reduce their dependency on imports and to promote self-reliance. As demographics evolve and infrastructure improves, health care is becoming more prominent.

quality services for citizens. Some of the laws in force in this regard include:

- Kenya Constitution (2010)
- Public Health Officers (Training, Registration and Licensing) Act
- Cancer Prevention and Control Act
- Public Health Act
- Health Act (No. 21 of 2017)
- Health Records and Information Managers Act (No. 15 of 2016)
- Higher Education Loans Board Act (No. 3 of 1995)
- Hire Purchase Act (Cap. 507)
- Housing Act (Cap. 117)
- Human Resource Management Professionals Act (No. 52 of 2012)
- Human Tissue Act (Cap. 252)
- Hydrologists Act (No. 19 of 2017)
- Private Health Sector Policy
- Medical Laboratory Technicians and Technologists Act (1999)
- National Hospital Insurance Fund Act
- Narcotic Drugs and Psychotropic Substances (Control) Act
- Kenya's Health Policy Framework (1994)
- Clinical Officers (Training, Registration and Licensing) Act (1988)
- Medical Practitioners and Dentists Act
- Food, Drugs and Chemical Substances Act
- Pharmacy and Poisons Act (1956).

1.6 The manufacturing industry and legal landscape

1.6.1 Importance of the manufacturing industry and its contribution

The manufacturing sector's contribution to Kenya's GDP averaged 10 percent annually between 2008 and 2014 and then declined to 9 percent in 2019, signaling a de-industrializing trend. The Big 4 Agenda is expected to reverse this trend and achieve a 15 percent contribution to GDP by 2022. Relative to other economic sectors, manufacturing has a high potential to generate more output and create jobs for many of those entering the labor market each year. This has also been observed in other countries through research. For example, according to the National Association of Manufacturers, which represents 14,000 member companies, every U.S. dollar invested in the U.S. manufacturing sector adds \$1.89 to the economy, and for every one worker in manufacturing, four others are hired in other sectors.

In 2018, the Purchasing Managers' Index for Kenya's manufacturing sector was 52 points, compared to 34.4 in 2017. The index, which measures the economic health of the private sector and monitors the performance of the manufacturing sector, is reported by Stanbic Bank Kenya and is based on five significant indicators: new orders, inventory level, production, supplier deliveries, and employment environment.

The equities market performance is considered to be an important barometer of the economic well-being of a country. In 2019, the Nairobi Securities Exchange turnover declined by 12.4 percent to stand at 153 billion Kenyan shillings, compared to 175 billion Kenyan shillings registered the previous year. The decline was attributed to poor performance in most large-capitalization stocks.

The national government seeks to boost exports through the National Export Development and Promotion Strategy,³⁶ which was introduced in 2018. The strategy aims to grow manufacturing exports at an average rate of 31 percent per year between 2018 and 2022. In the strategy, the government outlines certain sectors and subsectors of the manufacturing industry for priority development. These are: food, beverages, and tobacco; textile and apparels; leather and footwear; metal and allied industries; chemical and allied industries; pharmaceutical and medical equipment; plastics; light engineering; furniture; and motor vehicles and parts and accessories.

1.6.2 Big 4 Agenda to address credit-related challenges in the private sector

Access to credit, especially by the national government, has been on the rise. However, since 2014, there has been a decline in access to credit for the private sector.³⁷ This decline



has been attributed to the implementation of an interest rate cap that came into effect in 2016. From 2016, interest rates were capped at 4 percent above the Central Bank lending rate and banks were reluctant to lend. However, this interest rate cap was recently abolished. More people and businesses are now able to access loans, but at a higher interest rate. Though the interest rates on the loans are high, liquidity has increased and entities earlier locked out are now able to access financing.

The Central Bank of Kenya is reportedly working with banks to develop a banking charter so that banks will have a framework for determining their lending rates. To ensure that lending rates to customers decrease and access to credit increases, the Central Bank of Kenya has taken steps, such as to reduce the lending rate from 10 percent in March



2018 to 8.25 percent in October 2019. The introduction of the interest rate cap in 2016, which was removed in November 2019,³⁸ drove many financial institutions to provide credit to the government, crowding out important sectors of the economy, including the manufacturing industry.

Private sector credit from commercial banks is an important avenue for private investment in developing countries such as Kenya. Growth of credit to the private sector fell from a peak in 2016 of about 16 percent to 2 percent in June/July 2017. According to the Central Bank of Kenya's 2018 annual report, growth in banks' credit to the private sector improved from 1.5 percent in June 2017 to 4.3 percent in August 2018.³⁹ Even though credit to the private sector is picking up, the growth rate remains well below its historical average of about 19

percent. Nonperforming loans in Kenya have been increasing, which the Central Bank attributes to delayed payments by government agencies and the private sector and slow uptake of developed assets/units in the real estate sector. The rise in nonperforming loans indicates that businesses are facing cash-flow difficulties and are therefore unable to meet their business obligations, including repayment of debts.

Credit to the manufacturing sector is mainly from the commercial banks, and most of the projects approved through Kenya Industrial Estates are for small and medium-sized enterprises. The allocation of credit by public financial institutions to the manufacturing sector is dismal but is expected to change with an increased focus on the sector under the Big 4 Agenda.



Laws are continually being enacted and reviewed in all countries in response to a changing environment to protect a market/an industry and create conditions for better trade in goods and services.

1.7 The pharmaceutical industry in Kenya

Kenya's pharmaceutical value chain has three main stages: 1) production of inputs, 2) production of medicines, and 3) distribution (which includes wholesale and retail) to consumers. Value is evenly spread across these stages. The pharmaceutical manufacturing industry had a compound annual growth rate of 12 percent over the prior five years to 2019. The top five manufacturing companies export between 40 percent and 85 percent of their production, mainly to other East African countries.⁴⁰

1.7.1 Increased interest from pharmaceutical companies

International pharmaceutical companies are showing increased interest in setting up their manufacturing plants or expanding their footprint in Kenya. For example, Square Pharmaceuticals from Bangladesh is setting up a manufacturing plant in one of Kenya's export processing zones (EPZs) to grow its regional reach and meet

growing domestic demand in Kenya. The other entrant is Kolon Pharmaceuticals, one of South Korea's industrial conglomerates. Many other multinationals that have a presence in the country have also expanded their markets and product range by manufacturing branded generics. The demand for branded generics has become sizable, coupled with medicine procurement in large quantities by the donor community.

1.7.2 Reliance on imports for APIs, excipients, and packaging material

The Kenyan pharmaceutical sector has not yet moved towards the most complex activities of the value chain. Most companies still manufacture simple nonpatented products or rely on technology transfer agreements with foreign multinational manufacturers. Three companies produce raw materials (e.g., raw Artemether base) for API production, but these materials are destined for export, as the local capacity for processing raw inputs into APIs is underdeveloped. Most packaging materials are also

imported, despite attracting custom tariffs. Large and small pharmaceutical firms import about 60 percent and 35 percent of their packaging materials, respectively. The industry also imports the machinery and equipment for production from Europe and Asia, including the specialized labor for equipment installation, maintenance, and repair services. There is also a perception among pharmaceutical manufacturers that local packaging material is low quality.

1.7.3 Concentrated pharmaceutical manufacturing focused on limited drug types

Production of medicines by the pharmaceutical sector in Kenya is concentrated and dominated mostly by family-run businesses that focus on the simplest types of manufacturing. The largest 10 firms account for nearly 80 percent of local production, and they mainly produce unbranded generics. Most local firms compete in the same market segments with similar product portfolios.⁴¹ Over half of Kenyan firms are producing anti-infectives and are not tapping sufficiently into more lucrative immunological and cardiovascular markets that have a larger share in the region, but which need greater investments to manufacture. Local firms tend to produce simple dosage forms, such as plain tablets and capsules. While some firms diversify by producing syrups, suspensions, and creams (a fast-growing segment), only three firms produce injectable infusions and ophthalmic formulations that require technologically complex processes and stringent quality control standards such as sterile conditions.

1.7.4 The deployed local manufacturing capacity is underutilized

In Kenya, the average annual capacity utilization of local manufacturing firms' investment is about 60 percent. This underutilization of capacity is driven by supply-side issues, including operations management and foreign exchange losses, and a lack of reliable data on market demand and trends.⁴² Most firms cannot produce higher-value products because of a lack of technical expertise and financing for investment in advanced technologies and the requisite specialist workforce. The cost of production and equipment upgrades is high due to borrowing costs, which in general are about 5 percentage points higher than in India or Bangladesh.

1.7.5 Increasing reforms to support local manufacturing

The Movable Property Security Rights Act, 2017, provides for the creation of an electronic collateral registry for use by Kenyan banks and for the incentivization of saving institutions and pension funds to invest in the manufacturing sector. To grow the manufacturing sector, the government has tried to spur the increased purchase of locally produced goods by both the public and private sector. According to the Kenya Association of Manufacturers, all sectors in Kenya had limited access to government opportunities, and preference was given to foreign and imported goods and services.

However, in 2017, the Ministry of Industrialization, Trade and Enterprise Development launched the Buy Kenya Build Kenya strategy, which seeks to encourage Kenyans to buy and consume locally produced goods and services to support the domestic economy. The strategy promotes local production and pays special attention to local content and value addition requirements to enhance local market access for locally produced goods and services. Further, the Public Procurement and Asset Disposal Regulations provide a framework for the implementation of preference and reservation of quotas for locally manufactured goods and services. The Kenya Association of Manufacturers recommends that there should be an executive order on "Procurement of Public Goods, Work and Services by Public Entities," remedial measures in case of noncompliance, and the introduction of a local certificate of origin to verify authenticity as part of the implementation of the Buy Kenya Build Kenya strategy.

1.7.6 Need to address nontariff barriers to increase Kenyan exports

The manufacturers domiciled in Kenya target the EAC and COMESA as their main export markets for their products. However, exports to the EAC region are declining because of increased nontariff barriers, especially in relation to Tanzania and Uganda. These barriers include multiple cumbersome procedures for customs documentation and administration; nonrecognition of certificates of origin; varying standards and stringent application of sanitary and phytosanitary requirements; delays at border crossings; roadblocks; weighbridges; police checks; attendant costs; and unharmonized transit charges and procedures.

The Common External Tariff is outdated as the three-band tariff structure is not flexible enough to allow different levels of manufacturing value addition to take place.

Market opportunities for manufactured goods are, however, set to expand under the Tripartite Free Trade Area, which comprises the EAC, COMESA, and the Southern African Development Community. Kenya is also a party to the Africa Continental Free Trade Area, which offers a market of 1.3 billion people and a GDP of 340 trillion Kenyan shillings.

1.7.7 Legal landscape

The laws enacted by parliament and the resultant policy guidance provide the required foundation for organizations, bodies, companies, individuals, and other entities to conduct business in any country or region. Laws are continually being enacted and reviewed in all countries in response to a changing environment to protect a market/ an industry and create conditions for better trade in goods and services.

To achieve its objective of being a middle-income and industrialized country by 2030, Kenya has enacted new

laws and revised existing ones that no longer support this aspiration. The country wants to create the conditions to attract investment in the local pharmaceutical industry in order to meet domestic needs and export to regional markets. Kenyan laws that support the local manufacturing industry, and especially the pharmaceutical manufacturing sector, include the following:

- Anti-Counterfeit Act (2008)
- Anti-Counterfeit Regulations (2010)
- Capital Markets (Amendment) Act (No. 48 of 2013)
- Companies Bill (2015)
- Competition Act (No. 12 of 2010)
- Customs and Excise (Amendment) Act (No. 10 of 2013)
- East African Community Competition Act (2006)
- East African Community Competition Regulations (2010)
- Export Processing Zones Authority Act
- Industrial Property Act (No. 3 of 2001)
- Industrial Training Act (Cap. 237)
- Insolvency Act (2015)
- Investment Promotion Act (2004)
- Kenya Information (Amendment) Act (No. 41A of 2013)
- Kenya Institute for Public Policy Research and Analysis (2006)
- Kenya Institute of Curriculum Development (2013)
- Kenya National Qualifications Framework (2014)
- Kenya Ports Authority Act (Cap. 391)
- Land Act (No. 6 of 2012)
- Land Adjudication Act (Cap. 284)
- Land Consolidation Act (Cap. 283)
- Land Control Act (Cap. 302)
- Land Registration Act (No. 3 of 2012)
- Micro and Small Enterprises Act (2012)
- Microfinance (Amendment) Act (2013)
- National Industrialization Policy
- Partnership Act (No.16 of 2012)
- Public Private Partnerships (2013)
- Public Procurement and Disposal (Public Private Partnerships) Regulations (2009)
- Special Economic Zones Bill (2015)
- Standards Tribunal Practice and Procedure Rules (2012)
- State Corporations Act
- Understanding of East African Community Legislation on Standardization, Quality Assurance, Metrology and Testing Act.

In Kenya, intellectual property is protected by law. Various organizations are mandated to implement and enforce the Trademarks Act, Industrial Property Act, Seeds and Plants Tribunal under the Seeds and Plant Varieties Act, and Traditional Knowledge and Cultural Expressions Act. The Geographical Indications law is currently under review.

Intellectual property (IP) refers to the exclusive rights granted by the government over creations of the human mind, such as inventions, literary and artistic works, and

distinctive signs and designs used in commerce. IP rights are tremendously important for the pharmaceutical industry, given the huge investments required for drug discovery and development. The use of the IP system depends mainly on the business strategy of a company, its size, resources, innovative capacity, competitive context, and field of expertise. Research-based, innovation-led companies that seek to develop new drugs, improve or adapt existing drugs, or develop new pharmaceutical/medical equipment or processes, tend to rely heavily on the patent system to ensure they recover the investments incurred in research and development.

The World Intellectual Property Organization is the global forum for IP services, policy, information, and cooperation, and includes 193 member states. It is one of the 15 specialized agencies of the United Nations established following the 1967 Convention. The organization provides a platform for a balanced and effective international IP system that enables innovations and creativity for the benefit of all. A member state of the World Intellectual Property Organization since 1971, Kenya has four IP protection bodies, namely: 1) the Kenya Industrial Property Institute, 2) the Kenya Copyright Board, 3) Kenya Plant Health Inspectorate Services, and 4) the Anti-Counterfeit Agency. Other bodies, such as the Kenya National Innovation Agency and the National Research Fund, support the broader development of Kenya's innovation landscape by, for example, strengthening linkages between academia and business.

To ensure communities receive royalties for the use of their cultures and cultural heritage, governments, including Kenya's, are ensuring the protection and registration of geographical indications (goods from which a given quality, reputation, or other characteristic is attributable to its geographic origin), traditional knowledge, and cultural expressions.

Further, laws that protect against anticompetition practices through intellectual property, such as the Kenya Competition Act, 2010, proscribe restrictive trade arrangements or agreements that amount to the use of IP rights beyond the limits of legal protection. The Kenyan Constitution and the Consumer Act, 2012, also provide special protection for consumers by giving them the right to goods and services of reasonable quality. The main objective of IP rights is to allow manufacturers to distinguish their products and services from those of others and to empower consumers with choice. The Anti-Counterfeit Act formed the basis for the establishment of the Anti-Counterfeit Agency in 2010. It outlawed the production of counterfeits and enhanced the protection of IP rights. Despite this and many other initiatives undertaken, illicit trade remains a major concern in Kenya and has risen to alarming levels in recent years.



Kenya has a well-developed health sector and manufacturing industry, with the capacity to manufacture some health products (medicines and associated medical consumables) for both internal and export markets.

1.7.8 Overreliance on the global supply chain can undermine emergency response

Kenya has a well-developed health sector and manufacturing industry, with the capacity to manufacture some health products (medicines and associated medical consumables) for both internal and export markets. The country is also dependent on the global supply chain for medical equipment, certain drugs, and personal protective equipment.

When the COVID-19 pandemic hit, the country's reliance on the global supply chain for some of these items prevented a timely and effective response. The country joined others globally in seeking supplies of suddenly scarce medical equipment, diagnostic tools, medicines, and personal protective equipment. Kenya did not produce personal protective equipment and face masks before the COVID-19 crisis. It also did not have certified national standards to support the local manufacture and supply of personal protective equipment and face masks, and the Kenya Bureau of Standards only issued these national standards in April 2020.

Overreliance on the global supply chain for health products and technologies exposes a country to risks of interruptions or a shortage of items needed to respond to national emergencies and programs.

02





Methodology

2.1 Survey objective

The objective of the survey was to conduct a detailed study of the pharmaceutical sector in Kenya. Specifically, the survey analyzed existing value chains, players along the chain, their historical performance, growth trends, and challenges of entry into the market, expansion, and survival. The other objective was to determine critical issues along the value chain, including challenges to be addressed and opportunities that local pharmaceutical manufacturers can profitably exploit in the country and in regional markets.

2.2 Methodology

A mix of complementary methods was chosen to ensure the survey provided evidence to inform legal and policy reforms in Kenya needed to support current and new investments in the pharmaceutical industry for better performance. IQVIA conducted extensive data collection through:

- **Desk research.** Various sources were consulted, such as reports on the manufacturing and pharmaceutical industries, government laws and policy documents and reports, reports by critical stakeholders, data from the various Kenyan government websites, research articles from journals, and articles published in the electronic media. The desk research was conducted through a keyword-based search on search engines available in the public domain.
- **In-depth semi-structured interviews.** Interviews were conducted with 36 regulatory stakeholders and industry experts from Kenya and other countries. The interviews were guided by extensive discussion guides created for each stakeholder interviewed. The key stakeholders that were consulted are listed in Appendix 3.
- **Surveys with six investors.** A variety of investors (private equity investors, manufacturing organizations) with existing investments in Africa or who are planning to invest in Kenya's pharmaceutical industry were contacted. The objective was to understand investors' perceptions of Kenya and other African countries as investment destinations and build prospective target profiles for investments in the pharmaceutical value chain. The online link for filling out this survey was sent to 20 respondents through the World Bank team. The survey consisted of around 35 questions focusing on

identifying the key drivers and deterrents for choosing an investment destination, rating Kenya and other countries on essential parameters, and understanding the profile of investment already made. The survey questions are provided in Appendix 2.

- A *market pricing survey* of 30 pharmacies across three counties (Kisumu, Mombasa, and Nairobi). Various types of pharmacies were surveyed, such as pharmacies in high-end clinics, single pharmacies in high-end areas, single pharmacies in medium-income areas, pharmacies in low-end clinics, and pharmacies in low-income areas. The objective was to understand the variations in price to consumers and markups applied by pharmacies across different types of drugs (high priority/essential medicines, drugs which are exclusively imported, and drugs which are both manufactured in Kenya and imported). Field staff visited the pharmacies to fill out the survey. The survey consisted of a table to be filled out for 30 products. For each product, data needed to be provided on brand name, name of manufacturing company, dosage form/strength/pack size, price to the consumer, and markup. This survey is provided in Appendix 1.

The data collection exercise focused on developing an understanding of the existing situation in Kenya in general, and within the pharmaceutical manufacturing industry specifically.

The data collection exercise focused on developing an understanding of the existing situation in Kenya in general, and within the pharmaceutical manufacturing industry specifically. After the data-collection phase, the data were analyzed to assess the current state of the industry and the key challenges and constraints. Finally, certain policy-level interventions were proposed to mitigate the challenges and enable the government of Kenya to promote the local pharmaceutical manufacturing industry and attract investments into this domain.

2.3 Data management and analysis

The collected data (reports, research articles, news articles, data from websites, transcripts of interviews in the form of MS Word/PDF documents, and responses to surveys in the form of MS Excel spreadsheets) were stored securely. The



data underwent a rigorous process of analysis involving drawing inferences and synthesizing findings from the different sources.

2.4 Ethical considerations

The purpose, objectives, use, and benefits of the survey were explicitly explained to all respondents, and their informed consent was solicited before the interview session began, as appropriate. The anonymity of the responses and confidentiality of each respondent's identity were assured and ensured throughout the process of documentation by reporting aggregated findings. Findings, comments, and statements were not directly attributed to the interviewees. The consultants collecting



data observed standard ethical procedures and processes for conducting such interviews.

2.5 Challenges and limitations

The challenges and limitations of the data collection exercise are as follows:

- While the reports and articles available in the public domain were useful for providing background for this study, there was insufficient in-depth data to establish a nuanced understanding of the challenges faced by stakeholders in the pharmaceutical manufacturing industry.
- The in-depth interviews with key stakeholders were valuable for the richness and depth of the discussions, which formed an essential input for the key findings. However, the discussions also involved the stakeholders' personal biases and narrow perspectives.
- The survey conducted among the investors lacked sufficient number and breadth of experience of investment in multiple areas in the value chain.
- The study conducted among the pharmacies may have obtained responses which were considered to be "politically correct," that is, the response provided was the "acceptable" answer and not the "empirically accurate" answer.

03



Research findings

The survey findings have been divided into 10 sections that provide a comprehensive overview of the facets that make up Kenya's pharmaceutical industry. Each section provides an overview, outlines opportunities and constraints, and identifies areas of improvement so that Kenya can drive and sustain the growth of its local pharmaceutical industry.

3.1 The legal landscape

Kenya has supportive laws to inform function and practice in the health sector and the pharmaceutical value chain. The local laws of Kenya and other countries where Kenya manufactures goods are essential for companies and individuals who target regional export markets for their health products and services. Kenya has advocated for the review of laws in the EAC and COMESA regions to allow increased trade in goods and services, and to support the export of its expanding range of locally manufactured pharmaceutical products. Kenya has enacted several laws to support pharmaceutical manufacturers and investors. It continues to review regulations that undermine local manufacturing or exports to regional markets.

The following laws are of particular relevance to the pharmaceutical sector:

- The *Anti-Counterfeit Act, 2010*, created the foundation for the establishment of the Anti-Counterfeit Agency in 2010, outlawed the production of counterfeits, and enhanced protection of IP rights. Despite this, illicit trade (including of pharmaceuticals) remains a concern for business, government, and development partners.
- The *Industrial Property Act, 2001*, has been amended to strengthen the intellectual rights of individuals, communities, and organizations. However, knowledge of IP rights remains limited, and there are very few IP experts in Kenya. Kenya has aligned the act to exceed the minimum requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Countries that are party to the TRIPS Agreement are implementing TRIPS II, which will see increased protection for patented medicines and medical devices, as well as allow products to be used for more purposes without needing permission from the patent holders. TRIPS II will provide an enabling environment for local pharmaceutical manufacturers in Kenya to innovate in product formulation and product processes. In addition, TRIPS provides flexibility for

countries to use compulsory licenses to manufacture biosimilars and a window to undertake parallel importation of certain products whose patents are still in force to respond to the needs of national public health.

- Laws that protect against anticompetition practices through IP: The *Kenya Competition Act, 2010*, proscribes restrictive trade arrangements or agreements that amount to the use of IP rights beyond the limits of legal protection. The *Kenya Constitution, 2010*, and the *Consumer Act, 2012*, also give special protection to consumers by giving them the right to goods and services of reasonable quality. The main objective of IP rights is to allow manufacturers to distinguish their products and services from others, thus empowering consumers to choose.
- The *Pharmacy and Poisons Act, 1956*, regulates the function and practice of pharmacy in Kenya. It was amended in 2014 to clarify the governance and structure of the PPB, the pharmacy workforce, and pharmacy practice. The amendments outlawed the production, storage, and distribution of counterfeit and unregistered pharmaceutical substances and medical devices. In addition, the amended act introduced guidance on clinical trials of pharmaceutical products and medical devices.
- The *Health Act, 2017*, sought to consolidate action, institutions, and regulation on health, but it has not been fully implemented. Based on information provided by the PPB, the Pharmacy and Poisons Act was amended through the *Health Laws Act, 2019*.

3.2 The pharmaceutical regulatory landscape

Kenya has clear national guidelines and processes that define the requirements for registering a product, renewing registration, quality manufacturing, and the distribution, procurement, importing and exporting of health products. Figure 1 illustrates the key activities and processes in the pharmaceutical sector that are regulated.

3.2.1 Registration of products

To register a product in Kenya, pharmaceutical firms must comply with the set standards or requirements for a new product. Registration applications should include:^{43,44,45}

- **Application forms:** Electronic Common Technical Document and a summary of the dossier.
- **Three product samples** from the same batch and a batch certificate of analysis.
- **Certificate of pharmaceutical product** in WHO format.
- **Site master file** if the manufacturing facility is not approved by the PPB.
- **Registration fee:** \$1,000 for imported products, \$500 for locally manufactured products.
- **GMP inspection fee:** \$4,000 for foreign manufacturers and \$1,000 for local manufacturers.⁴⁶

Products are considered to be different if they have different active ingredients, dosage forms, strength, and proprietary names, and they need to be registered separately. However, if the product is the same, but the company wishes to change its packaging, no application is required. The product applications are evaluated on a first in, first out basis unless they qualify for fast-track registration to help address a national emergency. Once a product is registered, the registration is valid for five years. According to the PPB’s guidelines, it should take 12 months to process an

application. However, during the respondent interviews, industry stakeholders highlighted that it might take three to five years for a product to get registered.⁴⁷ This can also be attributed to the low skill level among manufacturers in preparing documentation and dossiers, which leads to the PPB needing to raise queries and seek additional information.

Locally and foreign manufactured products follow different registration processes. For both types of product, the dossiers are evaluated at two levels, with the second evaluator validating and finalizing the dossier. The reviewer of the provided registration dossier can request additional information, data, or samples, and the entity seeking registration is expected to respond within a specified period. When additional information is sought, the review process is halted until the response is received. If the response to the query or the item requested, on assessment, is deemed unsatisfactory, the product under review is disqualified and the application is rejected. During the respondent interviews, regulators and regional industry experts highlighted that local manufacturers lack sufficient knowledge and expertise

“But most of the time, you’ll find that especially our local manufacturers have no capacity to develop proper documents required.” – Regulator

FIGURE 1: KEY PROCESSES IN THE PHARMACEUTICAL SECTOR



to compile drug registration dossiers that meet the PPB's standards.

In special circumstances, fast-track approval may be granted if the product is locally manufactured or is a priority medicine, that is, if no alternative medicine exists or it is significantly safer or more effective than existing drugs for preventing or treating any serious or life-threatening diseases. Fast-track applications are generally processed within 90 working days.

3.2.2 Good manufacturing practice compliance landscape

3.2.2.1 Role of the PPB

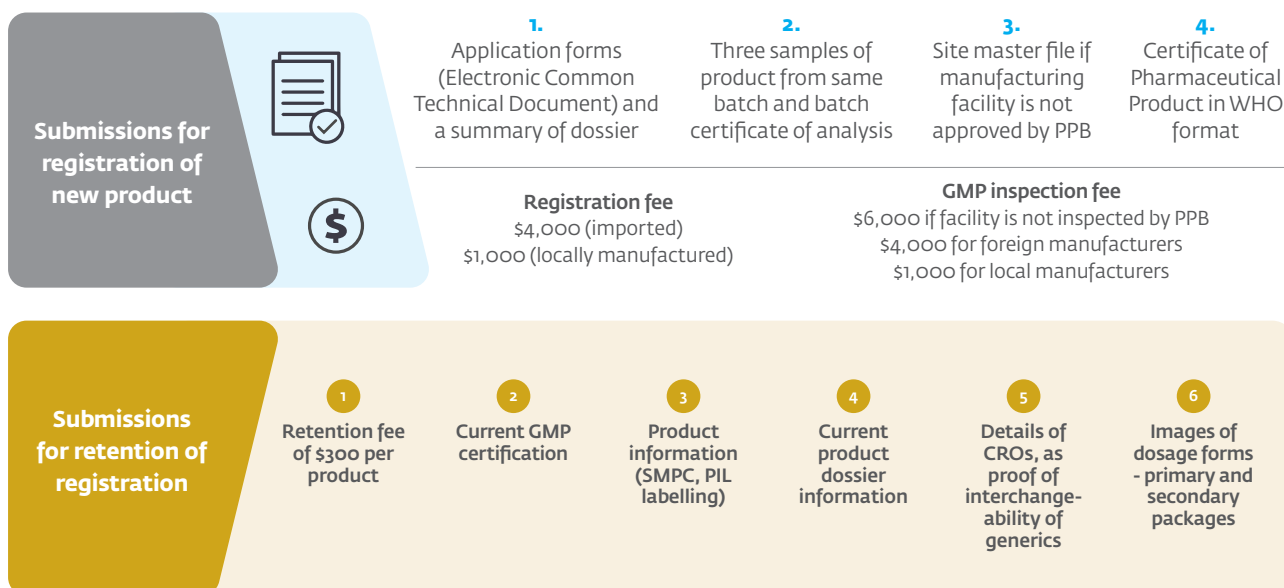
To ensure the availability of high-quality drugs in Kenya, the PPB and the Pharmacy and Poisons Act, 1956, require all pharmaceutical manufacturers to comply with prescribed good manufacturing practices (GMP). The GMP guidelines set by the PPB are based on WHO guidelines. The PPB reserves the right to verify that manufacturers comply with the GMP. This is done at the applicant's expense.

The PPB's GMP inspectors inspect new manufacturing sites to verify their compliance with local GMP and compile a report. If the site is found to be noncompliant, the applicant is required to address observed deficiencies within an agreed timeframe. Based on the compliance report, the Board may either approve the registration application or recommend that the identified gaps be addressed and request a re-inspection as appropriate. If the facility is still found to be noncompliant on re-inspection, the application is rejected. Similarly, if factories or facilities being considered for renewal of registration are found to be noncompliant, all their products are deregistered and withdrawn, and the plant, if local, is closed down to protect consumers.

The PPB's enforcement of GMP compliance has been negatively affected by its limited capacity. According to the PPB, the GMP inspectorate team consists of 31 members. One inspector has a PhD, 21 have a master's degree, and nine have bachelor's degrees. The GMP inspectors in the PPB receive training on data integrity and WHO and EAC GMP standards.

“The PPB gives incentives in the form of lower registration fees and a faster registration process for local manufacturers ... but evidently, timelines, in reality, remain very long and run into years.” – Manufacturer

FIGURE 2: PRODUCT REGISTRATION PROCESS AND REQUIREMENTS



The PPB does inspections of local manufacturers. To certify foreign manufacturers, the PPB conducts off-site inspections that include desk-reviews. This is specific to companies that have been inspected by stringent regulatory authorities and issued with certificates of GMP compliance, which must be valid. The PPB does not have sufficient inspectors, as a result of which it faces challenges in inspecting all foreign manufacturers within the stipulated time.

Kenya adopted the United Nations Industrial Development Organization-funded GMP roadmap (2012) and the suggested implementation plan for manufacturers to improve their quality standards. This program was able to improve the quality of local manufacturing to some extent, but not all the planned activities were fully implemented by industry players. The implementation plan sought to fix a baseline and move to meet the minimum GMP standards, before implementing corrective and preventive action and following up. There is a need for renewed encouragement of all manufacturing plants in Kenya to meet the requirements of the national GMP guidelines to ascertain their quality.

3.2.2.2 Post-marketing surveillance

Kenya has a clear protocol of undertaking post-registration and post-marketing surveillance (monitoring the safety of a pharmaceutical drug or medical device after it has

been released into the market). Kenya has an institutional and legal framework for pharmacovigilance. In practice, monitoring is subjective and inadequate to ensure market coverage. There is always a need to expand the scope of drugs or increase the frequency of testing.

The PPB has undertaken several post-market surveillance interventions targeted at antimalarial, anti-TB, and antiretroviral drugs. It undertakes post-market surveillances in collaboration with the NQCL, United States Pharmacopeia's Promoting the Quality of Medicines Program, WHO, CDC Kenya, Management Sciences for Health/Strengthening Pharmaceutical Systems, the Malaria Control Unit, and the USAID-funded Health Commodities and Services Management Program.

Various post-marketing surveillance reports indicate declining prevalence of poor quality medicines. In the most recent Rapid Results Initiative survey, conducted in 2018, multiple commodities were sampled and tested, such as antibiotics, syringes, condoms, analgesics, anti-hypertensives, antidiabetics, and contraceptives. In this survey a total of 785 samples were collected, which represented 250 registrable products of which 215 (86 percent) were found to be registered. A total of 214 of the 243 secondary samples that were subjected to laboratory testing complied with all the test parameters evaluated.

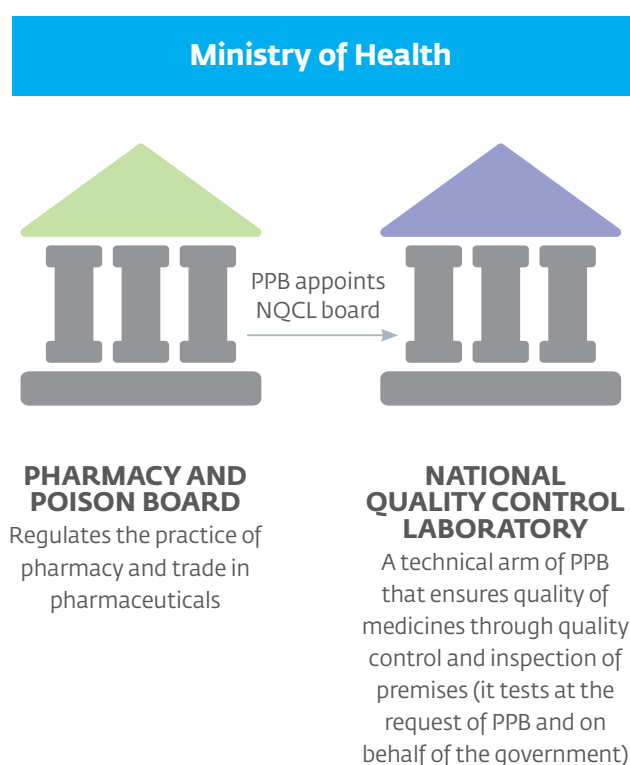
The number of pharmaceutical product samples analysed was 203, of which 40 were medical devices. Of these 203 samples, 98.2 percent complied with the specifications for uniformity of weight, 91.4 percent complied with dissolution test requirements, and 94.6 percent met specifications for content of active ingredient. All the samples complied with the test requirements for identification and pH (where applicable).

For medical devices, 90 percent complied with all the test parameters evaluated, while 5 percent did not meet at least one of the requirements for the dimensions tests and a further 5 percent failed to comply with specifications for the freedom from holes test.

However, the post-marketing surveillance report does not provide information on the corrective actions taken against manufacturers/retailers/facilities from which the substandard products were sourced. There should be provisions to take strict actions against manufacturers and supply chain actors for their failure to maintain the quality of drugs and other pharmaceutical products.

Further, there is a need to expand the post-market surveillance surveys to cover a greater range of products and to conduct them more regularly. For example, the PPB conducts annual surveys on antimalarial drugs. The frequency and scope of the post-market surveillance ought

FIGURE 3: PPB AND NQCL INSTITUTIONAL STRUCTURE



IMPROVING THE NQCL'S CAPACITY TO ANALYZE PRODUCT QUALITY

The NQCL and the PPB are two distinct government parastatals with clear mandates, but the PPB appoints the NQCL Board under Cap. 244 of the Pharmacy and Poisons Act, 1957. Both organizations are meant to collaborate but be functionally independent to ensure the independence of decisions related to the certification of the quality of health products and other

medical commodities in Kenya. Both parastatals report directly to the Ministry of Health.

The NQCL was formed to provide testing services to the PPB and other bodies. There remains a perceived conflict between the roles of and governance between the NQCL and the PPB. Their roles and responsibilities need to be clarified to reduce room

for conflict and support greater collaboration so that they can undertake their tasks effectively.

In addition, the NQCL will need to improve its recruitment and retention of skilled staff to operate the requisite equipment and carry out the necessary tests on provided samples to ascertain product quality.

“The laws exist for ensuring the quality of drugs in the market. The different bodies need to come together and fulfill their mandate and complement each other.” – Regulator

to be revised and enhanced or the quality of commodities and safety of consumers may remain a risk. These recommendations are in line with the recommendations proposed in the PPB's post-market surveillance report.

3.2.2.3 Role of NQCL

Kenya has a clear protocol of undertaking post-registration and post-marketing surveillance (monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market). In practice, monitoring is subjective and inadequate to ensure market coverage.

The National Quality Control Laboratory (NQCL) was established in 1992 as a body corporate under the Pharmacy and Poisons (Amendments) Act, Cap. 244. Although now a parastatal in its own right, the laboratory serves as the technical arm of the PPB, testing pharmaceuticals and medical devices to ascertain their quality. It was set up by the Kenyan government and has received WHO pre-qualification laboratory status.

The role of the NQCL is to conduct tests on samples at the PPB's request and send reports to the PPB on whether the samples meet acceptable standards or not. It is the PPB's responsibility to act according to the NQCL's report. Tests are conducted under two circumstances:

- During registration of products. Testing is done for all products under review for registration.
- During post-marketing surveillance. Quality surveys employ sampling techniques which ensure that representative samples are collected from all regions of the country and analysed. So far, the PPB has carried out post-market quality surveys of antiretrovirals, anti-TB medicines, antimalarials, reproductive health products, antimicrobial agents, products for erectile dysfunction, analgesics, medical devices, personal protective equipment, alcohol-based hand sanitizers, noncommunicable disease products, and maternal, neonatal and child health products.

The NQCL has functional equipment to conduct all tests, except for bioequivalence studies relating to special drugs like antiretrovirals (see box). It has the equipment to perform 3,000 to 4,000 tests a year. However, this capacity is underutilized, as the NQCL only conducts 600 to 700 tests a year for the PPB and other agencies in the country. Although it has high-quality equipment, the NQCL lacks sufficient skilled staff to perform its role effectively.

There is a need to address the challenges faced by the regulatory (PPB) and quality assurance/validation agencies (NQCL) to ensure the production and quality of

FIGURE 4: KEY CHALLENGES RELATED TO GMP



pharmaceutical products, and associated processes, meet standards to reduce risk to users and improve treatment outcomes.

Figure 4 depicts qualitative findings and observations drawn from stakeholder consultations with the private sector and the regulator in the public sector.

3.2.2.4 The role of manufacturers

Many local pharmaceutical manufacturers in Kenya have found it challenging to meet GMP requirements. Some of the challenges they face relate to the physical site and the quality management system (QMS). For example, if the entity is renting space, it is difficult to modify the space without breaking the lease agreement or undermining the structural integrity of the building.

Many manufacturers struggle to access capital from local banks to buy additional equipment and to expand and upgrade their infrastructure. They suggest that the limited access to financing could be due to banks' reluctance to provide loans to an industry mostly dependent on perceived risky business, especially those dependent on public sector tenders with uncertain payment periods. According to the IMF, access to capital was not an issue from 2007 to 2013.⁴⁹ This changed with the introduction of (now repealed) interest rate controls in 2016. A 2017 survey by the Central Bank of Kenya found that there was a 10 percent decline among 32 banks (representing 80 percent of the banking sector) in providing credit to micro, small, and medium-sized enterprises after the interest rate controls were introduced.⁵⁰

Local manufacturers identify lack of adequate knowledge and understanding of GMP as another challenge. Only few local manufacturers are GMP compliant.

MEDS also encourages manufacturers to achieve high-quality standards by auditing manufacturers' sites and validating the quality of commodities. It uses its quality control laboratory to validate the quality of commodities it procures for distribution from local manufacturers. The organization works with seven local manufacturers, and except for issues related to packaging, none of the products it has tested has failed on the drug quality parameters.

More needs to be done by the national regulatory agencies to improve the quality of commodities in the market in Kenya to both protect consumers and achieve better treatment outcomes. For example, government could provide incentives to companies that are GMP compliant. To address knowledge gaps, the pharmaceutical industry could design and introduce short-term and long-term professional courses in collaboration with academia and regulators. This will lead to increased awareness of GMP and increased industry capacity to enhance its quality control systems.

3.2.3 Distribution and retail trade

Distribution and selling of medical products are essential parts of the value chain in the supply of goods and services. Regulating the distribution and retail trade ensures that the quality of commodities in the supply chain is maintained, that accountable and fair practices are adhered to, and that illegal activity does not undermine access to health services.

The PPB is responsible for regulating the distribution and retail of pharmaceutical products in Kenya. It registers distributors, retail pharmacies, and pharmacists who apply and meet the set standards to conduct business in the pharmaceutical products value chain. All distributors and retail pharmacies are expected to be certified by the PPB to operate. However, Kenya's distribution and retail market is highly fragmented and not well regulated. Despite there being a high number of licensed retail pharmacies, there are also many unlicensed ones that compete with the legitimate ones in the same market space. The PPB inspects the premises of those involved in trade and takes action against those that do not comply with set standards, but it has insufficient capacity to effectively regulate pharmacy trade and practice in Kenya.

All retail pharmacies are required by law to have a premise license and a qualified superintendent pharmacist licensed by the PPB. However, the full enforcement of this law remains a challenge in the country.

The USAID's 2019 Kenya Health Assessment report estimates that there are about 6,000 unregistered pharmacies in Kenya. Most of these unlicensed retail pharmacies obtain their supplies from redistributors and wholesalers.⁵¹

Data on file from the PPB paints a different picture of the number of unregistered pharmacies in the country. Based on the PPB's survey of 5,672 retail pharmacies conducted between July 2019 and June 2020, 20 percent of pharmacies did not comply with the Good Distribution Practices. Although this sample did not cover all the pharmacies in the country, it is recommended that the PPB assesses/surveys all the pharmacies and retail outlets to validate their registration and practice. This would go a long way to provide the necessary evidence for decision making and strengthen the country's efforts to improve practice standards and the quality of drugs in the supply chain.

There is also a need to strengthen the capacity of the PPB and other complementing agencies to enforce practice standards and regulations. The full implementation of the

Joint Health Inspection Checklist, gazetted on March 21, 2016, is expected to help further regulate retail pharmacy trade and practice. The checklist will require regular audits of all public and private health facilities (including retail pharmacies). Those that meet the required standards will be certified, while those that do not will be closed.

3.2.4 Exports

The process of exporting medicines from Kenya is similar to that of importing them into the country (see Figure 5) but in reverse. However, there are additional requirements in the destination country:⁵²

- A preferential certificate of origin is granted by the Kenya Revenue Authority for exports destined for countries that have a trade agreement with Kenya.
- A non-preferential certificate of origin is granted by the Kenya National Chamber of Commerce and Industry for exports destined for countries without a trade agreement with Kenya.

Additional formalities (registering with the appropriate local authority and payments) are required in the destination country in the absence of a harmonized system. However, according to the PPB, the harmonization process is under way in the East African region. Joint registration will be recognized in East Africa. This will be supported by a common technical document for South Sudan, Tanzania Mainland, Kenya, Uganda, Burundi, Rwanda, and Zanzibar. Eventually, regulators plan to cross-recognize inspections undertaken and reports issued by peers in any of the member countries. A respondent in the pharmaceutical manufacturing industry reported that Ethiopia and Tanzania take much longer than other countries to register products from Kenya. Products locally manufactured and in use in Kenya face few challenges in obtaining registration in Uganda and Djibouti.

Several bodies oversee function and practice in Kenya's pharmaceutical industry. Some of them fall under the Ministry of Health, while others report to other ministries. Bodies that oversee IP matters, manufacturing and practice licensing, quality assurance, taxation, and environmental

FIGURE 5: REGULATORY REQUIREMENT OF IMPORT AND EXPORT PROCESS



assessments all have a role to play in regulating the industry, yet they are in constant tension because Kenya lacks a harmonized approach.

3.3 Capacity to respond to national health needs in a globalized world

The accelerating pace of globalization has led to the creation of geopolitical, economic blocs in regions that bring constituent countries together to improve their viability in terms of market size and to increase their buying power, competitiveness, and negotiating leverage with the countries and regions that dominate trade. In addition, opening up countries and markets to global trade in goods and services (including health products and technologies) has driven:

- Industry consolidation to achieve scale
- Choice of location to undertake research, develop products, and manufacture based on the presence of requisite skills, low labor costs, and other factors of production.
- Integration of supply chains.
- Cross-recognition of product registration and certification in countries and regions that meet certain agreed standards.

Many countries that had clusters of medical products and technology companies have seen most of them relocate their production to other countries and regions or disappear during buyouts to consolidate, improve scale, reduce competition, and achieve vertical integration. The United States and the United Kingdom, once key hubs for drug research and development and manufacturing, have seen their footprint in the sector decline and are now mostly dependent on companies in mainland Europe and China for certain supplies such as insulin and heparin. While the production of medical products at a low-cost location abroad is attractive to investors and beneficial to the host country, in certain circumstances, this can limit other countries' ability to respond effectively to national emergencies.

The COVID-19 pandemic, which saw the rapid spread of the coronavirus during the first quarter of 2020, exposed the risks inherent in integrated global supply chains, and the consolidation of manufacturing health products and commodities in one region or a few countries in the world. China and India are key manufacturing hubs (for foreign/offshoring and indigenous companies) for health products and commodities (medical equipment, medicines, personal protective equipment, and consumables) for the export market. When COVID-19 hit, these countries enacted policies that forced companies domiciled in them to prioritize their limited supplies for the national response, regardless of whether they had contractual obligations to their other clients globally. Only threats of

reciprocal action by the United States and other countries forced them to reconsider supply (including ventilators, personal protective equipment, and Hydroxy Chloroquine) to global clients and the global supply chain. Moreover, the countries that had allowed their companies to offshore their medical products and equipment manufacturing to China, or are dependent on imports, are encouraging greater production in-country in response to the challenges identified during the COVID-19 crisis.

Kenya has a fairly developed and functional capacity, within its borders, to manufacture some health products (medicines and associated consumables) for both the local and export markets but is also dependent on the global supply chain for medical equipment, drugs, and personal protective equipment. When the COVID-19 pandemic triggered a crisis, the country's reliance on the global supply chain for some items undermined a timely and effective response. Countries around the world were competing to outbid each other to get access to a limited supply of the required medical equipment, diagnostic tools, medicines, and personal protective equipment. Kenya did not have certified national standards to support the local manufacture and supply of personal protective equipment and face masks. The Kenya Bureau of Standards only issued these national standards in April 2020.

It is evident that overreliance on the global supply chain for health products and technologies exposes a country to risks of interruptions or a shortage of items needed to respond to national emergencies and programs.

To ensure that Kenya has the capacity to respond to national health or medical needs and demand in the region, a viable, functional manufacturing base for essential items needs to be developed and maintained.

3.4 Economic enablers in Kenya

Kenya has a well-articulated framework to grant and monitor existing incentives in line with the country's development goals and desired culture. In 2019, Kenya launched the Kenya Investment Policy, which is a comprehensive and harmonized policy to guide the attraction, facilitation, retention, monitoring, and evaluation of private investments both at the national and county levels.

The policy is guided by seven core principles, which emphasize the need for openness and transparency, inclusivity, sustainable development, economic diversification, domestic empowerment, global integration, and investor centeredness.

Figure 6 outlines the incentives that the Kenyan government uses to attract investors.⁵³

Other steps that Kenya has taken to encourage investments include establishing a one-stop shop to support investors in setting up businesses, and establishing export processing zones and special economic zones.

3.4.1 Establishment of one-stop shop to support investors in setting up businesses

Multiple government bodies have come together to operate the one-stop shop to streamline processes and help organizations seeking to set up businesses in Kenya. The services offered at the one-stop shop include: advice on registering a company; facilitation of obtaining a business permit license and other approvals; advice on tax regimes, and registering for value-added tax (VAT/personal identification number) and how to file returns; advice on obtaining licenses for environmental impact assessments; assistance with obtaining power connections; advice on specialized schemes and investment incentives available; and assistance with business name searches.

3.4.2. Establishment of export processing zones and special economic zones

Export processing zones

Export processing zones (EPZs) are designated parts of the country that are meant to create an enabling environment for export-oriented investments and promote and facilitate such investments. There are over 40 gazetted zones in Kenya at different stages of development. They are located in Nairobi, Voi, Athi River, Kerio Valley, Mombasa, and Kilifi. These zones are managed and promoted by the Export Processing Zones Authority (EPZA).⁵⁴

The EPZA acts as the primary licensing and regulatory body on behalf of the government and collects the necessary information and data from the companies. It seeks to minimize bureaucracy and administrative procedures, and facilitate licensing, setup, and operations of EPZ projects. This includes exempting businesses from compliance with various laws such as the Import, Export, and Essential Supplies Act; the Standards Act; the Industrial Registration Act; the Factories Act; and the Statistics Act.

FIGURE 6: SNAPSHOT OF TYPES OF INCENTIVES FOR INVESTORS

National government incentives	General provision
Newly listed companies can enjoy reduced corporate tax for 3-5 years	Annual investment allowance for buildings based on type of building
Companies can carry forward IOSCs to offset against future taxable profit	Once-and-for-all investment deduction for cost of building and machinery
	Investment deduction allowing on machineries and equipment
	Exemption from VAT
Special Economic Zones Authority (SEZA) incentives	Export Processing Zones Authority incentives
10-year tax holiday	Exemption from corporate income tax for 10 years
15% corporate tax for another 10 years	25% corporate tax after 10 years
Duty and VAT exemptions	Exemption from VAT and custom duties on import of machinery and raw material
Single license	10-year withholding tax holiday on dividends
Exemptions from stamp duty	100% investment deduction on new investment on EPZ buildings

EPZs provide an attractive investment opportunity for export-oriented businesses. There are no restrictions on who can invest in these zones. The scheme also offers a wide range of fiscal, physical, and procedural incentives to ensure lower-cost operations, faster setup, and smoother operations. See Figure 6 for an overview of the fiscal and procedural incentives for EPZs.

Special economic zones

To spur economic growth in the country, increase employment opportunities and attract foreign investment, the Kenyan government enacted the SEZ Act in 2015. The act aims to support the growth of businesses by providing an enabling environment, such as an integrated infrastructure facility, and additional incentives, as well as removing any barriers. The SEZ Authority is the regulator of all SEZs. It is responsible for designing, approving, establishing, developing, operating, promoting, and regulating SEZs. It also issues licenses and implements government policies and programs. It is in charge of determining the investment criteria and investment thresholds for the businesses in the zone and maintains records of the enterprises and residents operating in each zone.

Three types of licenses are issued to run a business in an SEZ in Kenya: operator license, developer license, and enterprise license. The various incentives given to businesses in an SEZ are tax exemption, duty exemption, work permit facilitation, and protection and repatriation of profits.⁵⁵

Kenya's Vision 2030 identified SEZs as a key pillar for the country's industrial transformation and diversification. Through these zones, the country aims to boost competitiveness in targeted manufacturing sectors, including pharmaceuticals, and attract private investors by ensuring regulatory and administrative predictability, quality industrial infrastructure, and market access.

Sectors that are covered by SEZs include:

- **Freeport zone:** A designated area at the port where goods introduced there are regarded to be outside the customs territory (EAC countries).
- **Free trade zone:** A customs-controlled area where goods are offloaded for transshipment, storage, and possibly bulk breaking, repacking, sorting, mixing, trading, or other forms of handling, excluding manufacturing and processing.
- **Industrial park:** A zone with integrated infrastructure to facilitate manufacturing and processing industries.
- **Information and communications technology park:** A zone to facilitate the information and communications technology sector, its services, and related activities.
- **Business processing outsourcing:** This zone provides

outsourcing services such as back-office support services in human resources, finance, accounting, and procurement.

- **Agricultural zone:** A zone that facilitates agricultural sector and related activities.
- **Business service park:** A zone that promotes service sectors such as business processing outsourcing, call centers, management consulting, advisory services, and other associated services.
- **Livestock zone:** Zones for companies in the livestock industry involved in activities such as livestock marshaling and inspection, livestock feeding, refrigeration, deboning, and manufacturing of veterinary products.
- **Science and technology park:** SEZs for the science and technology industry.
- **Other types of SEZs** include tourist and recreational zones and areas for conventions and conference facilities.^{56,57}

The SEZ Act provides several benefits to investors, including exemptions from taxes and duties on all SEZ transactions under the Excise Duty Act, Income Tax Act, East Africa Community Customs Management Act, and Value Added Tax Act; an investment deduction for capital expenditure on buildings and machinery for use in an SEZ; permission for SEZ companies to employ expatriates for up to 20 percent of the total workforce; and lower corporate tax rates of 10 percent for the first 10 years and 15 percent for another 10 years.

3.4.3 Ease of doing business

The World Bank's Doing Business 2020 Report ranked Kenya 56 out of 190 countries, up five places from the previous year. Among African countries, Kenya was ranked fourth, after Mauritius, Rwanda, and Morocco. Kenya's improved ranking is due to its improved performance on certain parameters.⁵⁸ Specifically, the government has:

- **Embraced digitization**, especially in its business regulatory reforms. It increased transparency in the construction permit process by placing the requirements online and making them publicly available.
- **Simplified the process of providing VAT information** by enhancing its existing online system to improve access.
- Implemented an **online land rent financial management** system on the e-Citizen portal, enabling property owners to determine the amount owed in land rent, make online payments, and obtain the land rates clearance certificate online.
- **Made it easier to register property** by reducing the time it takes to get a search done and process a title. Registering

TABLE 2: CORPORATE INCOME TAX IN EPZS AND SEZS

Installments	EPZ Tax Rate	SEZ Tax Rate
First 10 years	-	10%
Next 10 years	25%	15%
Thereafter	30% or 37.5%	30% or 37.5%

property takes 43.5 days in 2020, down from 49 days in 2019. However, an additional requirement to generate a payment slip was introduced.

- **Strengthened minority investor protections** by expanding shareholders' role in company management, introducing additional disclosure requirements for related-party transactions, and increasing director liability. Kenya was ranked first globally on this parameter.
- **Strengthened the legal rights of borrowers and lenders** by creating a unified, modern collateral registry for movable property, and introduced a functional and secure transactions system to improve access to credit. The new law regulates functional equivalents to loans secured with movable property, such as finance leases and fiduciary transfer of title.
- **Improved access to credit.** Kenya's ranking in credit access improved from eighth in 2019 to fourth in 2020 as a result of introducing online registration, modification and cancellation of security interests, and public online searches of the collateral registry.
- **Improved insolvency regulations.** Kenya introduced improved provisions on the treatment of contracts during insolvency. It introduced a new law that allows the continuation of contracts with those supplying essential goods and services to the debtor, giving the administrator the power to continue, renegotiate, or cancel.
- **Made it easier to pay taxes** by simplifying tax compliance processes, reducing the number of tax filings, and introducing flexible payment schedules of the amounts owing. In 2020, 24 payments per year are required compared with 25 in 2019.

3.4.4 Preferential public procurement

Kenya's public health sector obtains its commodities mostly through the centralized procurement body, Kenya Medical Supplies Agency (KEMSA), which procures, stores, and distributes health products (including medicines and nonpharmaceuticals) for use in public health facilities and programs. To encourage the local industry to build capacity to manufacture, the government has sought to provide incentives. In this regard, the Kenya Public Procurement and

TABLE 3: CHANGE IN LEVY AND IMPORT DECLARATION FEE

Product	Railway development levy	Import declaration fee
Raw material	1.5% (unchanged)	2% to 1.5%
Finished products	1.5% to 2%	2% to 3.5%

Disposal Act, 2015, states that "the procuring entity may grant a margin of preference of up to 15 percent in the evaluation of bids to candidates offering goods manufactured, mined, grown, and extracted in Kenya." This act also describes the pre-qualification of the supplier and the tendering process. Pre-qualification is a process instituted to identify entities that meet the standards and are certified for compliance with process and product quality. This helps them to access public sector tender business or to service emergency procurement without going through the usual requisite lengthy validation process.

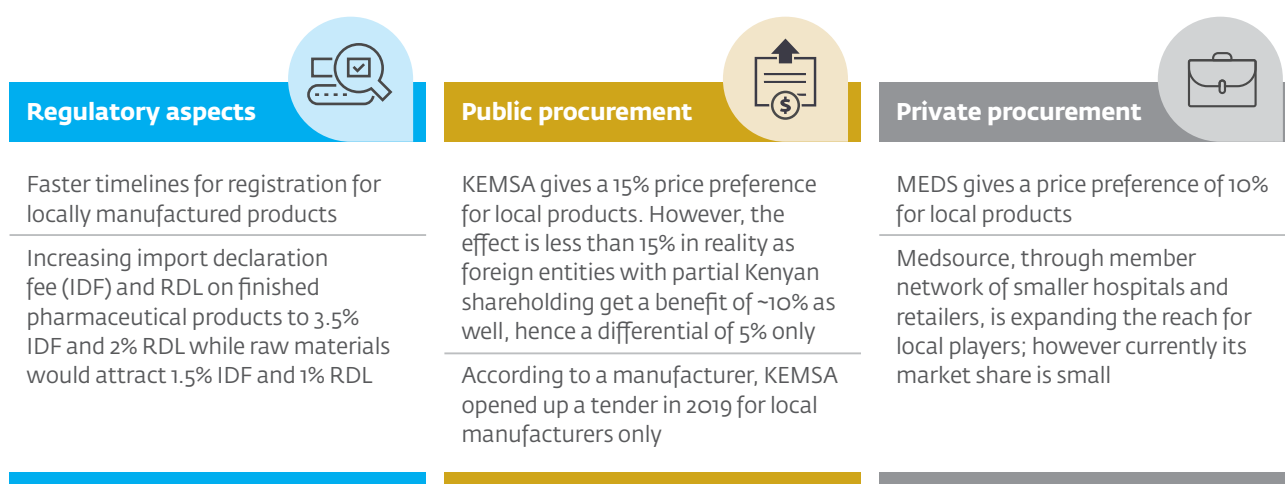
Surveyed pre-qualified local manufacturers indicated that they had not benefited much from the promised incentives, despite being certified compliant. They have not been given preference in tender awards even when their bid was within the stated acceptable range of 15 percent above the bid price of a foreign competitor on the same product or range. As a policy, KEMSA offers a 15 percent price preference for entities that can demonstrate significant local content or sometimes to imported products supplied by companies with a local presence. KEMSA, however, needs to work closely with the industry, and provide national policy-directed preferential treatment in procurement to local manufactured goods and share planning data/reports, including procurement plans.

In addition, the requirement by development partners who support commodity procurement for the public health sector that potential suppliers be WHO pre-qualified has limited the opportunity for many local manufacturing companies to engage in the public tender business in Kenya. In the absence of WHO pre-qualification, local manufacturers are ineligible to participate in tenders for the procurement of donor-backed drugs sourced by KEMSA. Only three local pharmaceutical manufacturers in Kenya are WHO pre-qualified. In the event of a stock-out or emergency, the need for an urgent procurement response overrides many other considerations, and many local manufacturers do supply their products to KEMSA.

3.4.5 Incentives, import levies, and tariffs

Kenya has significant capacity to locally manufacture and supply health products and associated consumables. The country also imports a significant amount, in volume and value, of innovator products⁵⁹ and generics to meet demand

FIGURE 7: INCENTIVES FOR DOMESTIC MANUFACTURERS



and for export to regional markets. To ensure the country can provide and improve access to health services, the government has, over the years, levied no import duty or VAT on imported medicines and raw materials meant to support the manufacturing of medicines. A 16 percent VAT is, however, charged on packaging materials imported by industry suppliers. This can be claimed back if proof can be provided on their sale, delivery to the client, and use in the pharmaceutical manufacturing industry.

The lack of import duty on medicines has helped create an import-driven market and has, over the years, undermined local manufacturing of pharmaceutical products in the country. The government has sought to reduce the proportion (in volume and value) of imported medical products to support the local manufacturing industry.

The fees levied on imported pharmaceutical products include the PPB levy: 0.75 percent, import declaration fees: 3.5 percent (increased from 2 percent to 3.5 percent by the Kenya Revenue Authority), railway development levy: 2 percent (recently increased from 1.5 percent), port charges: fixed fees, insurance of goods: 0.5 percent, and clearing agent: fixed fees.⁶⁰

Figure 7 outlines various incentives provided by the Kenyan government to encourage and support investment in the production and supply of quality local pharmaceutical products.

Globally, countries have sought to support and protect their industries (including the aircraft, steel, and farming industry) by giving incentives, levying duties, or placing tariff barriers on imports. When other countries identify this as unfair trade practice, however, they could institute reciprocal measures targeted at the same industry or others to force their peers to yield. Examples include the United States and the European

Union on Boeing and Airbus, and the United States and Canada on aluminum and steel. A government can use various incentives, import duties, or tariffs to support and protect its nascent or small industry, but as the industry grows, it becomes more visible, exposing the country to potential reciprocal measures or unfair trade-related litigation under the World Trade Organization agreements on trade.

Incentives can thus be costly to a country, resulting in lost tax revenue or lost income from exports of goods and services when other countries institute reciprocal measures. Incentives may be used as a stopgap measure to support industry, but they are not feasible as a broad, longer-term intervention. There is, therefore, a need to encourage the local pharmaceutical industry to identify and implement strategies that improve their capacity to meet GMP standards and obtain WHO pre-qualification, improve product quality, and improve financial performance and overall competitiveness in the targeted market spaces over the longer term.

3.5 Kenya's pharmaceutical market, stakeholders, and supply chain

3.5.1 Pharmaceutical market size and trends

In 2019, Kenya's pharmaceutical market was estimated to be worth \$1 billion and projected to grow at 6.6 percent annually until the end of 2021. However, some industry experts feel that the size and value of the Kenyan market is understated because of a lack of data on parallel imports and medicines smuggled into the country. Kenya is currently the largest producer of pharmaceutical products in COMESA. According to a 2018 report by Kenya's Ministry of Industrialization, Trade and Enterprise Development, the target markets for exports of Kenya's pharmaceutical products are COMESA, the EAC, and the rest of Africa. The total value of this market

is estimated at \$13 billion. Currently, Kenya is only able to export on average \$63 million to this market each year.⁶¹

The demand in Kenya for pharmaceutical products is expected to rise substantially in the coming years due to population growth, national health-care-related initiatives (especially the program to expand universal health coverage), increasing health-seeking behavior by citizens on account of better access to information with rising literacy and greater use of the internet, and the increased buying power of citizens as a consequence of the country's strong economic growth and performance.

The Kenyan government's rollout of a universal health coverage program is expected to improve citizens' access to health services, increase demand for medicines, and spur growth in the local pharmaceutical industry. The local market is mostly dependent on imported products for innovator medicines and brands, while local manufacturers focus on the production and provision of generic medicines. Further, the market is slowly transitioning from branded innovator products to lower-priced generics mainly in response to the price sensitivity of the medical insurance industry. The insurance industry has aggressively sought to lower provider costs, and drug prices have been an area of

focus to help, in turn, reduce their loss ratio.

3.5.2 Key pharmaceutical stakeholders

The pharmaceutical sector in Kenya has many key stakeholders. These include government ministries, national regulators, product manufacturers, importers, distributors, wholesalers, and retailers.

3.5.2.1 Research institutions

Research institutions are important stakeholders and will play a critical role in helping the country realize its dream of being a pharmaceutical manufacturing hub in the East African region. Vision 2030 envisions Kenya becoming an industrialized, middle-income country by 2030. Science, technology, and innovation are recognized as essential components for achieving this vision, as they will spur industrialization and economic growth from a solid knowledge base. The harmonious performance of government, academia, and research institutions has been shown to lead to the industrial application of innovations and their adoption by the customers.

To stimulate and sustain investment in research and development, the Kenyan government has established tax incentives. The importation of research equipment was zero-

FIGURE 8: KENYA PHARMACEUTICAL MARKET AND DRIVERS

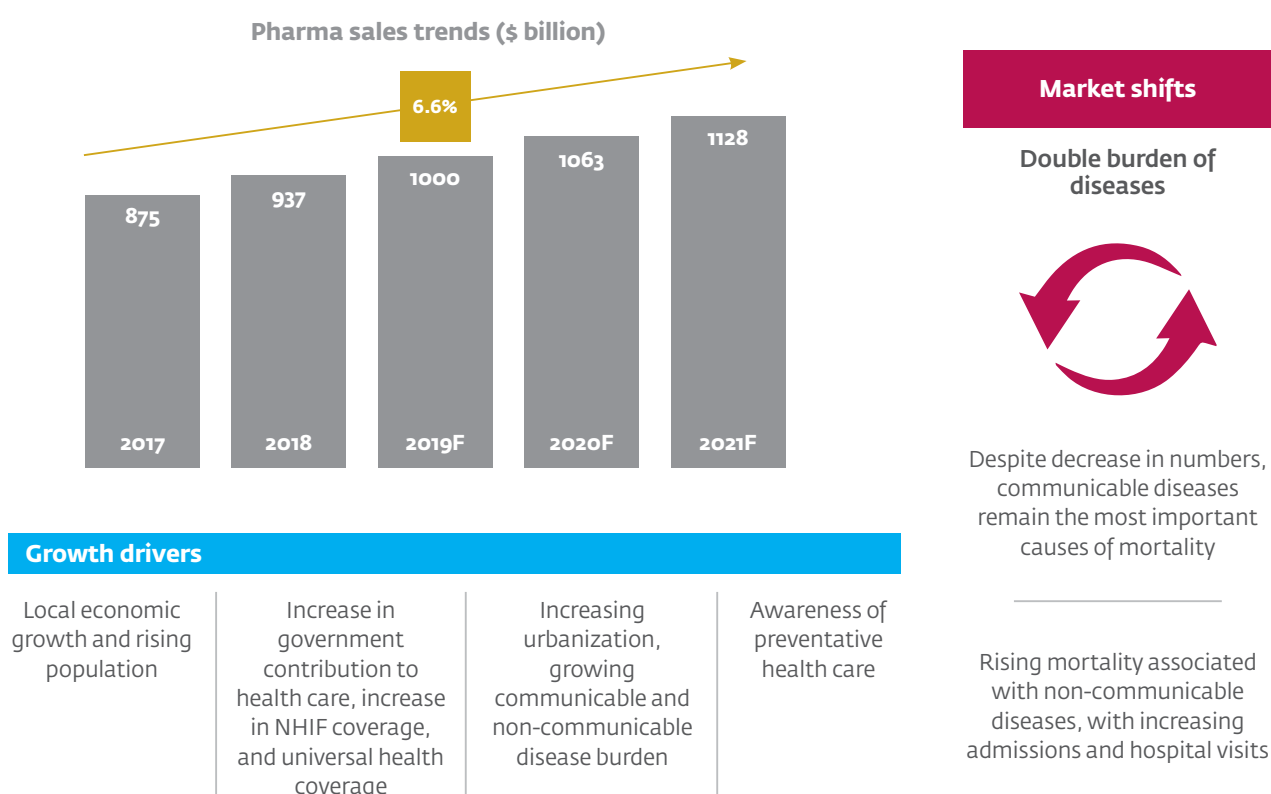
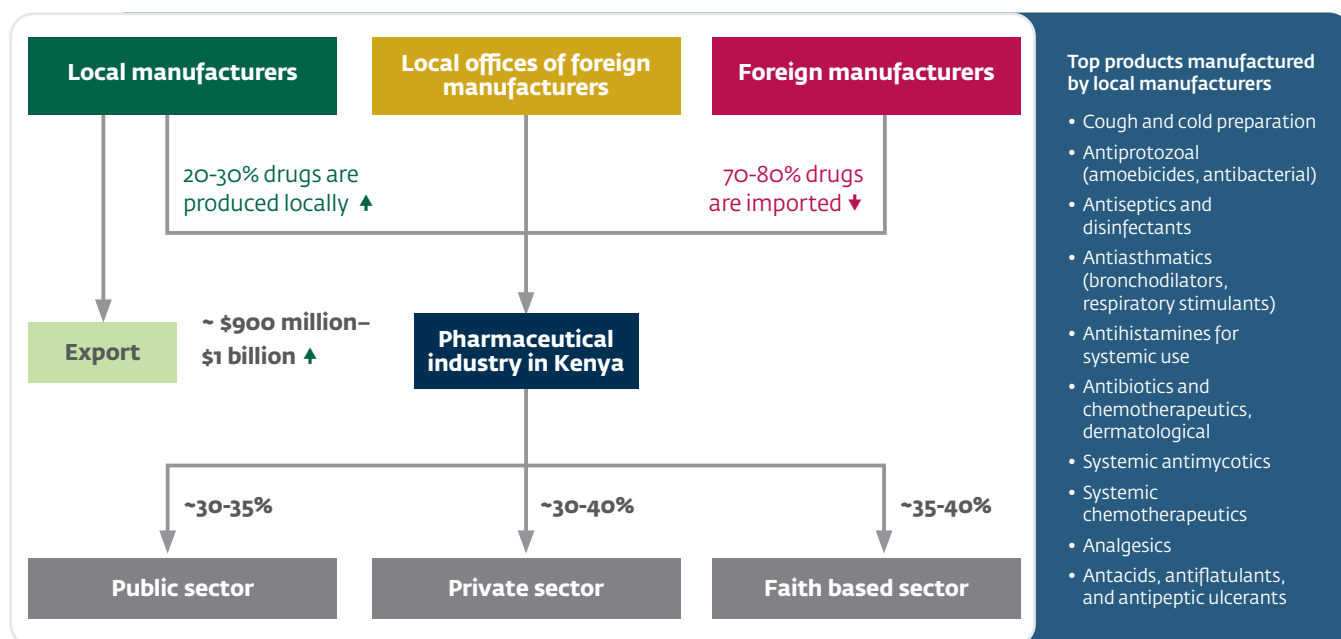


FIGURE 9: KENYAN PHARMACEUTICAL MANUFACTURER LANDSCAPE



rated, and tax incentives have been implemented to attract foreign direct investment in research and development.

The Big 4 Agenda and Kenya's Constitution also highlight the importance of homegrown technologies in national progress, upholding IP rights in the country. The Science, Technology, and Innovation Act, 2013, was enacted to provide a framework for strengthening national research and innovation. The act created three strategic organizations, namely the National Commission of Science, Technology and Innovation, the National Research Fund, and the Kenya National Innovation Agency. The Ministry of Education has established links between academia and industry, including the private sector, to facilitate translation of research findings.

Other institutions within the country that promote and implement research include:

- Africa Institute for Capacity Development
- Academic Model Providing Access to Healthcare
- KEMRI - Welcome Trust
- The Kenya Institute for Public Policy Research and Analysis
- Kenya Industrial Research Institute
- Kenya Medical Research Institute
- Pan African University Institute for Basic Sciences, Technology and Innovation

3.5.2.2 Academia

Higher education strategy in Kenya focuses on increasing access and equity, improving the quality and relevance, and addressing the governance and accountability of education

and learning. The Ministry of Education has prioritized the following initiatives:

- Establish the Open University of Kenya and deliver 30 percent of degree programs through an e-learning mode by 2022.
- Increase the gross enrollment ratio in university education from 7 percent to 15 percent.
- Enhance the quality and relevance of training and research to meet industry needs.
- Increase access to programs in science, technology, engineering, and mathematics to 60 percent of the student population.
- Create opportunities for academic staff to acquire PhDs and appropriate pedagogical skills.
- Enhance equity and inclusion in university education, especially for females and students from low-income families, and strengthen the governance and management of university education.

To date, 32 training institutions have been approved by the PPB in Kenya, comprising seven universities for training pharmacists and 25 diploma colleges for training pharmaceutical technologists. Many of these pharmacy graduates will serve in the pharmaceutical industry upon completing their studies. The performance of the industry depends on the skills of these graduates who go on to work in the pharmaceutical value chain.⁶²

3.5.2.3 The manufacturers

Kenya has 33 active pharmaceutical manufacturers and

therefore it is an essential center for pharmaceutical manufacturing in the EAC region. Kenya's market share for domestic medicines amounts to about 30 percent (in terms of value), while Uganda's and Tanzania's shares amount to 20 percent and 12 percent, respectively.⁶³ The size variation in these markets is due to their complexity, the number of human resources in service, the volume and value of products produced, and the type of ownership. In Kenya, there are locally owned companies, large multinational corporations, subsidiaries, and joint ventures.

According to local industry experts, there is increasing acceptance and consumption of locally manufactured products in Kenya. This perspective is supported by IQVIA's pharmaceutical sales data in the private retail sector. The market share of local companies in the total private sector retail market increased from 11 percent in 2017 to 12 percent in 2019. This is expected to be a beneficial trend for domestic pharmaceutical manufacturers.

Local manufacturing companies can produce simpler dosage forms. They even have a higher market share for select drugs such as generic flucloxacillin antibiotics and nonnarcotic analgesics. In these molecules, the market share of local players is as high as 68 percent.⁶⁴ There is, however, a need for local manufacturing companies to improve their capability to enable them to produce more complex dosage forms and serve many more therapy areas than their current

TABLE 4: PHARMACEUTICAL WORKFORCE STATISTICS

2019/20

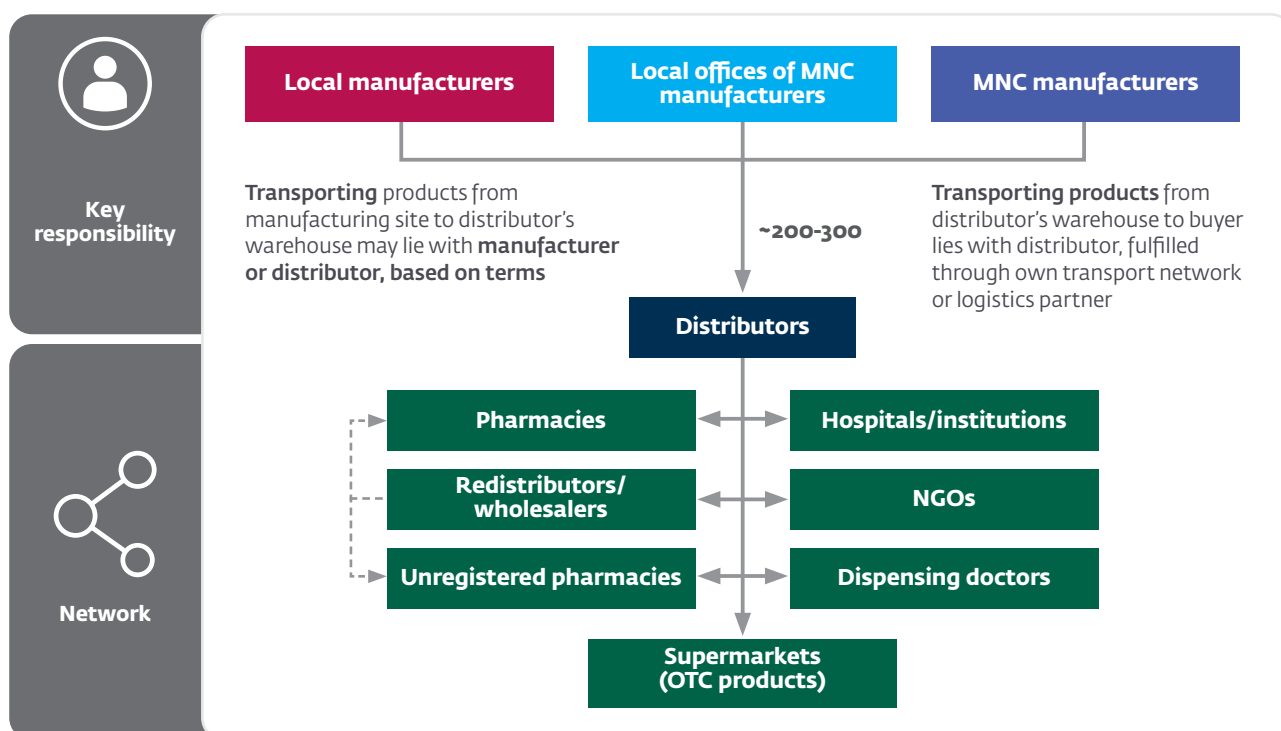
Registered pharmacists	3,830 ⁷⁰
Registered pharmaceutical technologists	10,800 ⁷¹
Unregistered pharmacies	6,000 ⁷²

and potential clients will demand in future.

3.5.2.4 The distributors

The distributor organizations that are duly registered and regulated by the PPB perform the distribution role, procuring products from the manufacturers they represent and supplying hospitals, clinics, and retail pharmacies in the country. Some distributors work exclusively with local manufacturers, a few work with foreign manufacturers, and some work with both. To expand their market and improve their turnover, over time, some of the distributors in Kenya have gone beyond their traditional storage and logistics services role. They have ventured into importation and provision of contracted sales and marketing services (especially to small foreign generics companies).

FIGURE 10: STRUCTURE OF PHARMACEUTICAL DISTRIBUTION NETWORK IN KENYA



According to a 2019 report by USAID and Palladium, there are few large wholesalers that account for a significant share of pharmaceutical supplies to both public and private not-for-private sectors.⁶⁵ Another report by GIZ in 2016 suggests that there are over 30 large distributors in Kenya.⁶⁶ According to IQVIA estimates, there are between 200 and 300 distributors in Kenya, most of whom deal in smaller quantities.

3.5.2.5 Retail pharmacies

The retail market in Kenya is currently fragmented and unregulated, with multiple unregistered pharmacies active in the value chain. During the survey, respondents provided varying estimates of the number of unregistered retail pharmacies operating in Kenya. The presence of unregistered pharmacies has been well documented in several studies and reports.⁶⁷ According to USAID's Kenya Health Assessment report (2019), there are more than 6,000 unregistered pharmacies in the country.⁶⁸

Unregistered pharmacies have created a market for counterfeit medicines. According to the USAID report,⁶⁹ total annual sales of counterfeit drugs are estimated to be \$100 million. Unregistered pharmacies' inability to legally source quality products from registered distributors has forced them to seek out and sell counterfeit or substandard products, undermining government's effort to improve access to quality drugs and contributing to poor clinical outcomes.

3.5.2.6 Hospitals

Traditionally, hospitals and pharmaceutical manufacturers have had a transactional relationship, but this is now changing to a strategic one where both are focused on patient outcomes and overall better health for communities. Public and private hospitals in Kenya have significant influence within the health value chain and form a significant customer group for the pharmaceutical sector.

Global policies on ethics and compliance for big pharmaceutical companies in market practice have also influenced the relationship between hospitals and the pharmaceutical industry, limiting the extent to which they can interact.

There are also growing opportunities for partnerships in clinical trials, research, and value-based contracts that improve access to medicines for patients, including novel therapies. Investment in primary health care by public and private hospitals has resulted in more facilities being set up in geographically diverse locations within the country and the implementation of electronic, fully integrated health management systems that facilitate clinical research in multiple locations.

Increased scrutiny by health insurance companies provides an opportunity for risk-based contracts with the pharmaceutical industry designed to link drug prices to drug performance with actual patients. The high rate of mobile technology adoption in Kenya also

provides opportunities for consumer-driven initiatives that can leverage the combined strengths of hospitals and pharmaceutical companies to improve the customer experience and clinical outcomes, and lower costs, especially for chronic disease management.

3.5.2.7 Export markets

The export markets are a key opportunity for driving the growth of Kenya's local pharmaceutical industry. The EAC and COMESA regions are key destinations for the products of Kenyan manufacturers. According to a report by the United Nations Conference on Trade and Development (UNCTAD),⁷³ the East African pharmaceutical market is worth about \$5 billion, only 30 percent of which is accounted for by local manufacturers. This presents an opportunity for local manufacturers in Kenya who produce health products of the required quality at scale and to meet the demand of the citizens of the EAC countries.

The goal is to drive Kenyan exports of pharmaceutical products to the EAC, COMESA, and the rest of Africa, where the total market size of imported pharmaceutical drugs is estimated to be \$13.6 billion. Between 2014 and 2016, Kenya was only able to export an average of \$63 million to this market. Assuming 5-percent share of total import market to be coming from Kenya, then this market for pharmaceutical products will translate to exports from Kenya worth \$678 million.⁷⁴

3.5.3 The pharmaceutical supply chain in Kenya

There are three fairly distinct supply chains in the country, as detailed below.

3.5.3.1 Public sector channel

The Kenya Medical Supplies Authority (KEMSA) is the agency tasked by government with forecasting demand for, procuring, storing, and facilitating the distribution of health products (equipment and commodities) to meet the needs of the public sector providers. KEMSA currently has two large, well-equipped warehouses in Nairobi. These two warehouses are on lease but KEMSA is building its own large modern warehouse with financing from the Global Fund to ensure the commodities it receives are well stored to maintain their quality and efficacy. KEMSA has a time-tested, award-winning web-based logistics management information system, which the 47 counties use to place orders with KEMSA for supply.

Upon authorization by the chief officers in the county department of health to ensure finances are committed to pay bills when they become due, county pharmacists transmit orders and monitor their processing and delivery against mutually agreed performance indicators, including lead times and order-fill rates. Upon receipt of an order, if the customer account is in good standing, the order is processed on computer and transmitted to staff on the

warehouse floor to select and assemble the goods for delivery. Warehouse staff use a handheld barcode reader to scan individual items selected for the order. The barcode reader matches the batch number and expiry date on the order form, automatically adjusting the stockholding in the system when that item is issued.

KEMSA procures, stores, and supplies health products financed by the Kenyan government and development partners for national programs. All public health facilities in the 47 counties are required by law to procure their products from KEMSA. The national Level-6 referral hospitals, universities, and research institutions can procure health products and technologies from certified sources, in line with general policy, without going through KEMSA.

The lengthy bureaucratic processes involved in public procurement are intended to provide a fair opportunity to all role players, spur competition to lower unit prices, and improve transparency. However, they can result in delayed receipt of needed commodities, thereby impacting KEMSA's ability to meet its promise to clients on lead-times and order-fill rates. To address these procurement process-related

challenges, allow more flexibility in tendering and award, and improve its overall performance, KEMSA has sought support from the public procurement regulatory authority, the National Treasury, and the Ministry of Health to help it advocate for a change in the law on public procurement. In particular, KEMSA wants to be able to award multiple contracts to ensure an alternative or leverage exists if one supplier fails to meet a contractual agreement. The full rollout of universal health coverage is expected to increase the role of the public sector in health service delivery, with more people seeking services from public institutions.

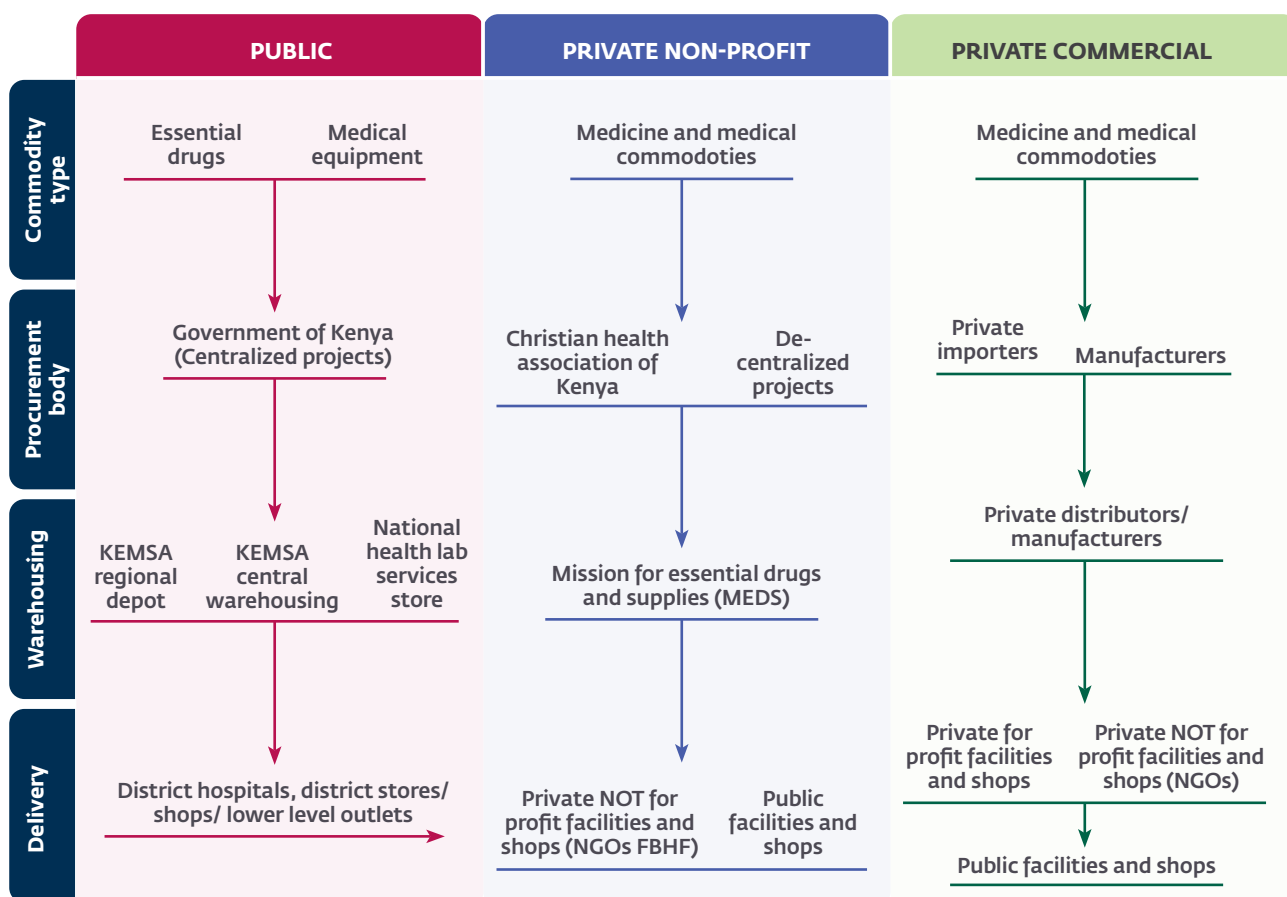
3.5.3.2 Private commercial (for profit) channel

The stakeholders in the private commercial space include importers, manufacturers, distributors, retail pharmacies and shops, private health facilities, and private NGO facilities.

3.5.3.3 Faith-based channel

This channel mostly comprises the faith-based civil society organization sector and is served by the Mission for Essential Drugs and Supplies (MEDS). MEDS procures, stores, and distributes products to the faith-based market. It also

FIGURE 11: KENYA PHARMACEUTICAL SUPPLY CHAIN



provides quality assurance and health advisory services to programs supported by development partners and the government, especially the testing of products to validate their quality. After KEMSA, MEDS is the alternative or second-preferred provider of health commodities to county public health facilities.

MEDS is a not-for-profit entity and, therefore, only charges a markup to cover the costs of its operations. At present, it works with seven local manufacturers. One of MEDS's key goals is to bring down unit prices to improve access to pharmaceutical products by using its industry leverage. It gives a 10 percent price preference to local manufacturers and, at times, splits its tender to multiple organizations to reduce risk. Payment delays are the main challenge MEDS faces in providing supplies to faith-based health providers.⁷⁵

Warehousing and distribution of pharmaceutical products

The pharmaceutical supply chain in Kenya is fairly sophisticated and supports the health service in fulfilling the country's quest to ensure all citizens have access to quality health care. However, some challenges have undermined its ability to perform its role effectively. Bureaucratic processes and the lack of adequate regional public and private sector warehousing facilities, distribution management systems, and transport infrastructure up to the last mile cause significant delays in shipment and receipt of medicines at the points of service.

Storage facilities

KEMSA has several regional warehouses in Eldoret, Garissa, Kakamega, Nakuru, Meru, Kisumu, Nyeri, and Mombasa. Of these, only Kisumu was renovated (and opened in 2020) to have full cold-chain capacity to hold all types of pharmaceutical products. The rest have varying levels of capacity to hold drugs requiring a cold chain, and most have low capacity refrigeration units. They largely hold KEMSA's excess stocks (commodities that are not temperature sensitive) and provide limited holding facilities for counties without capacity to store their safety stocks (the amount of stock required to cover the delivery period).

A current challenge is that many places across the country lack adequate public and private sector storage facilities that meet standards. This lack of storage capacity undermines drug supply and contributes to poor adherence to inventory best practice. In general, the lead times and responsiveness of suppliers in the pharmaceutical sector is impacted by insufficient functional regional storage facilities. Customers are essentially served from Nairobi. Poor storage conditions, compounded by a poor transportation system, contribute to the deterioration in the quality of products over time.

To address this, there is a need to encourage investments in rental warehousing facilities throughout the country where that business is viable. These facilities should

have the necessary cold chain for the effective storage of pharmaceutical products, including those that require refrigeration.

Distribution systems and practices

The private sector distribution network is severely fragmented, and there is no incentive to consolidate or create meaningful coordination between private and public players. Ad-hoc distribution strategies and poor planning undermine access to quality products by the secondary clients and end-users. Lack of adequate warehousing facilities and inadequate skills in staff within the supply chain is the leading cause of underutilization or misuse of commodities.

There is a need to encourage the public and private sectors in the procurement and warehousing business to develop mechanisms for joint use of their existing, and sometimes redundant, capacity in warehousing and transport systems to reduce costs and improve their competitiveness and margins. It is possible to compete and, at the same time, cooperate where it makes business sense to do so.

According to stakeholders, the lack of demand-forecasting skills among private distributors and the lack of sharing of demand data with manufacturers is often the reason for overstocking and stock outs. In addition, late payment or failure to pay by government, and especially by county governments, for commodities supplied by distributors and procurement agencies contributes to poor services. The anticipated risk of late or no payment forces suppliers to hedge and provide commodities to the government at higher prices.

To improve Kenya's distribution system, there is a need to encourage investors to develop logistical capabilities to

FIGURE 12: QUALITY OF RAILROAD INFRASTRUCTURE SCORE

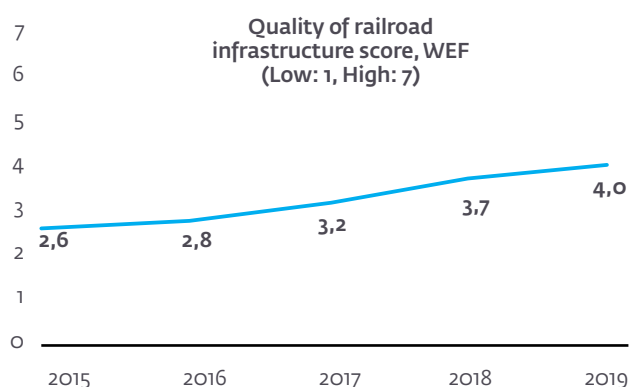
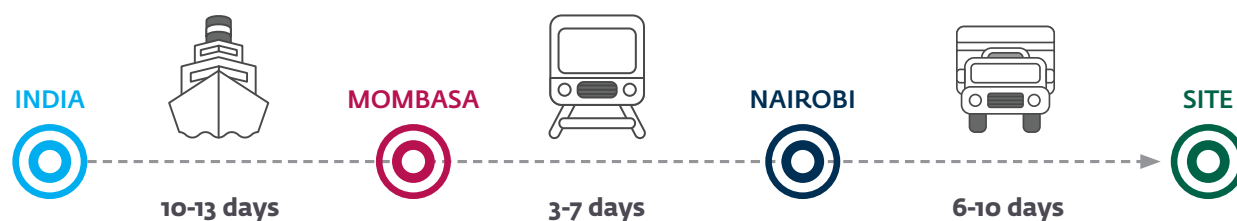


FIGURE 13: TIMELINE OF TRANSPORT OF MATERIAL FROM INDIA TO MANUFACTURING SITE IN KENYA



transport certain health commodities without breaking the cold chain for quality and efficacy. Private organizations can also develop and offer demand-forecasting services at pay-per-engagement to those that need them to help anticipate demand and undertake quantification to inform commodity procurement, warehousing, and transport of the items to customers.

Transport infrastructure

Kenya improved its ranking on the quality of overall transport infrastructure from 72nd in 2015 to 56th in 2017 (out of 138 countries) on the World Economic Forum's Global Competitiveness Index. It ranks behind Namibia (52nd) and South Africa (29th) but is ahead of most other Sub-Saharan African countries. Roadways carry 93 percent of all freight and passengers. The country has a road network that is about 177,000 km in aggregated length.⁷⁶

The roads in urban areas and the main highways are often congested with passenger cars and heavy transport vehicles. This not only slows down the movement of goods and people but damages the standard bitumen roads, shortening the period for which they were designed to last. The poor physical condition of roads causes the frequent breakdown of vehicles, increased travel time, and congestion.

The rural road network (especially in the hard-to-reach areas) becomes a great challenge during the rainy season.⁷⁷ Poor quality of the rural road infrastructure and the relatively high transaction costs for ground and air transport impose cost burdens on firms involved in logistics services, and this negatively affects their overall competitiveness. Most pharmaceutical products are either transported by road or air, and the cost of freight increases the eventual unit cost to end-users. Further, transporters and logistics partners are unable to track consignments, especially in places without good communication network coverage, including mobile phone networks. Poor infrastructure and delays lead to an inability to service markets faster and to lost value in terms of the shelf life of products.

According to the Global Competitiveness Index 2019, Kenya has made some progress in improving the quality and efficiency of its railroad infrastructure.⁷⁸

Kenya's government needs to improve the country's transport system (especially the road network) to ensure pharmaceutical products are delivered in a timely manner and without damage, whether these products are needed to provide health services to citizens or for shipment to export markets. The use of air transport to deliver pharmaceutical products is faster but more expensive, especially when used for the haulage of liquids or bulky products.

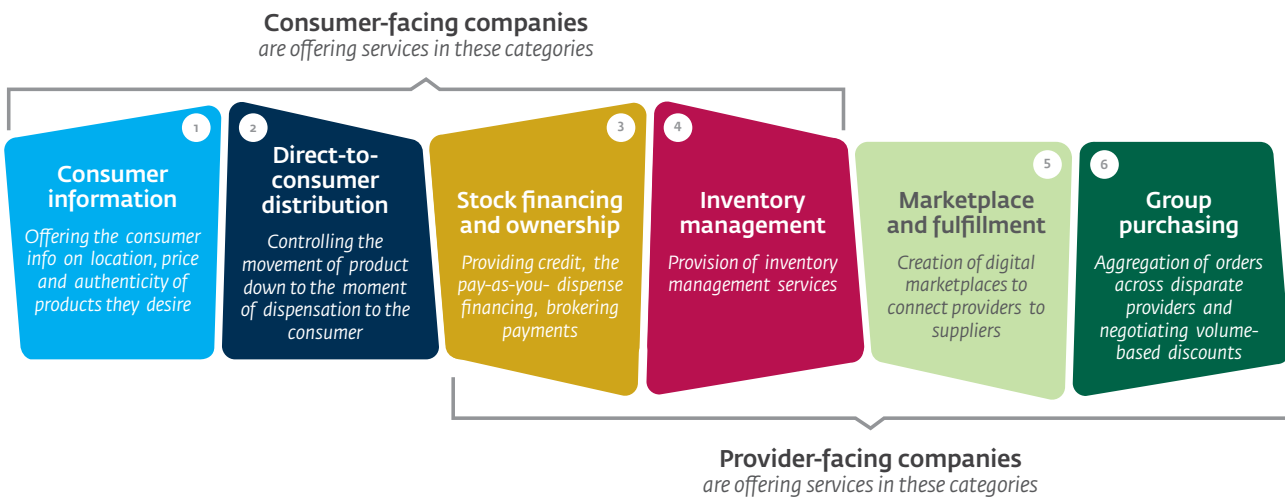
Procedural delays impact lead times

The procedural delays and bureaucratic hurdles at the ports of entry and the weighbridges on the highways are often cited as causes of long lead times experienced for imported goods, which are one of the inputs for pharmaceutical product manufacturing.

Some respondents in the sector reported that the time taken to ship an item from India to Mombasa is less than the time it takes to transport an item from Mombasa to the manufacturing site in Nairobi. The bureaucratic process involves multiple agencies, requisite paperwork, clearances, and procedures and is said to be inefficient and often painfully slow. The actual time it takes to transport an item from Mombasa to a manufacturing site located in Nairobi by road is six to eight hours. Any unfortunate delay in receipt of inputs increases costs of production and lowers productivity because the product may be slowed down or halted, and yet staff have to be paid for no work done. Further, the delayed conversion of these inputs into products for sale undermines early income realization and could lead to loss of customers or markets that the marketing team took months or years to develop. Many respondents in the manufacturing subsector cited the transport or shipment of goods from Mombasa to Nairobi as a huge challenge.⁷⁹

There is a need to identify and address these clearance and transport challenges. It is important to carry out regular feedback surveys among the stakeholders who use the clearance system and transportation network to identify what needs to change or be improved for better service delivery to facilitate optimal business performance in the country and encourage greater investment.

FIGURE 14: TYPE OF INNOVATION IN THE PHARMACEUTICAL SUPPLY CHAIN



3.5.4 Key innovations in the supply chain space

The Import for Health report (2019) identified new corporate startups in the region that provide services in the supply chain to address distribution challenges and improve access.

The abridged description of the startups and the type of services they provide are as follows:

- **MedSource:** Launched in 2018, this is a member-driven marketplace for health products, which offers enhanced quality control and stock-financing solutions. It has more than 3,500 health products on its marketplace. It is currently working with 160 facilities, 24 of which are hospitals. MedSource is a private, for-profit company that facilitates ordering by licensed pharmacies, clinics, and hospitals by connecting them to manufacturers and key agents. It has negotiated volume-based discounts. It also provides its members with stock-financing solutions. This approach allows for more efficient purchasing by negotiating best prices and providing price transparency “to the last mile,” credit guarantees (up to 80 percent) to retailers, and data visibility to distributors or manufacturers. The platform does not control delivery, allowing providers to select their distributors or a MedSource partner.
- **Shelf Life:** This is the first organization to offer full-service inventory management at the level of community pharmacies, allowing pharmacies to sell on consignment. It has 50 pharmacy customers in Kenya.⁸⁰ It provides community pharmacies with full inventory management on a subset of their fastest moving products. Shelf Life drivers go to the pharmacy or customer to manage stocking, forecasting, and reordering on behalf of the pharmacists. Pharmacies pay for stock only once the products sell. This approach removes the risk for the pharmacy of overstocking, understocking, expiry, and re-allocation. Shelf Life’s set monthly pricing on products also protects pharmacies from the unpredictability (volatility and seasonality) of commodity pricing.
- **Maisha Meds:** Maisha Meds offers small, rural pharmacies inventory management and will be launching stock financing. It is present in Kenya and can deliver commodities anywhere in the country in 24 hours at the cost of \$3. Maisha Meds works with rural pharmacies and clinics on an Android-based application to manage sales and inventory and source quality medicines. The platform works online and offline and provides automated demand-forecasting and ordering capability. It has contracted with suppliers and manufacturers and can offer medicines at 18 percent less than the average market price to partnering pharmacies. Its platform carries MyDawa-

The startups offering services in the pharmaceutical distribution space include:



branded generics, other prescriptions, over-the-counter medicines, cosmetics, and self-test products.⁸¹

- Kasha:** This is an e-commerce platform company that offers women in limited-resource settings better access to low-cost, high-quality health products. It focuses on women's health and personal care and allows products to be purchased and delivered confidentially. Kasha provides a medium for manufacturers to reach women and get market insights on untapped customer segments.
- MyDawa:** A licensed e-pharmacy and supply chain solution provider for pharmaceutical products, operating across the supply chain. Its platform carries MyDawa-branded generics, other prescriptions, over-the-counter medicines, cosmetics, and self-test products.⁸² It sells a range of products through its online platform and has a product-tracking and -packaging system to ensure the quality of products from the point of origin to distribution. The products carried on the MyDawa platform are about 20 percent cheaper than market price. It is also working in rural areas to help improve access to medicines for chronic disease management, via pharmacists who keep 10 percent of the sales margin.

The nascent online retail pharmaceutical business in Kenya has come under scrutiny by the government and the PPB because of the risk of abuse of medicines. In the not-too-distant future, a policy direction will be issued and pharmaceutical legislation will be amended to accommodate and help regulate the use of e-platforms in the pharmaceutical commodity supply chain.

3.6 Human resources and operational landscape

3.6.1 The human resources landscape

The Kenyan pharmaceutical sector presents numerous employment opportunities along the entire pharmaceutical value chain. These opportunities are expected to increase if more investors (including multinational companies) are attracted to set up manufacturing bases in Kenya. For example, Square Pharmaceuticals is setting up a manufacturing unit in Kenya. This will not be the largest plant in the region but will create employment opportunities for many people. The list of possible job opportunities is summarized in Figure 15.

“If there were more jobs in the production division, then students would have more preference for the industrial pharmacy segment.” – Manufacturer

FIGURE 15: POSSIBLE JOB OPPORTUNITIES FOR THE PHARMACY GRADUATE

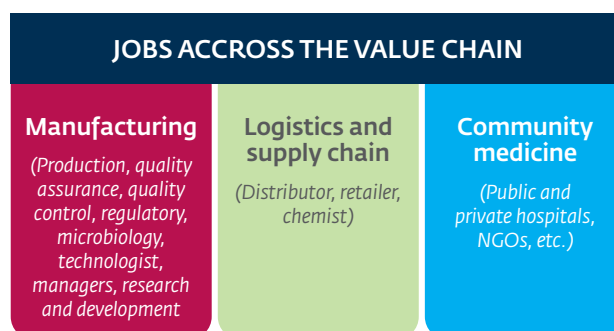


FIGURE 16: PHARMACEUTICAL WORKFORCE RATIO

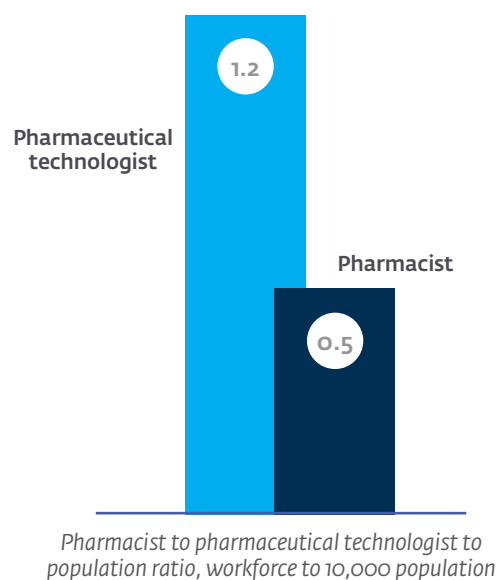
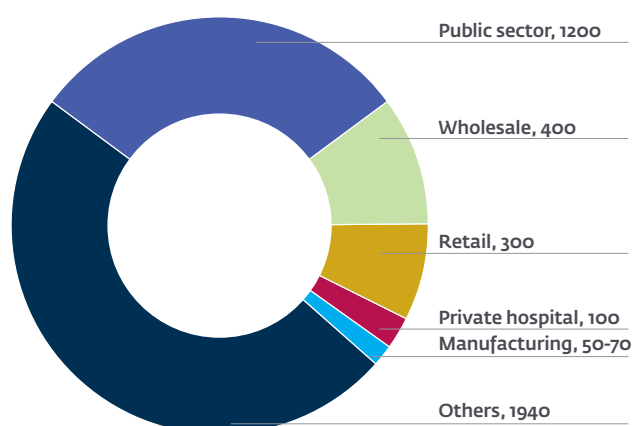


FIGURE 17: SPLIT OF PHARMACISTS ACROSS SECTORS



Workforce statistics: Two cadres of pharmaceutical personnel are recognized by law: pharmacists and pharmaceutical technologists. The PPB is the regulatory body for pharmacy education, certification, and practice. According to PPB data, there are 3,830 registered pharmacists and 10,800 pharmaceutical technologists in Kenya.⁸³ According to the Kenya Health Workforce Report, the current pharmacist-to-population ratio in Kenya is 0.5 per 10,000, while that of pharmaceutical technologists is 1.2 per 10,000. WHO recommends developing countries have a pharmacist-to-population ratio of five pharmacists per 10,000.⁸⁴

According to stakeholder consultation with the Pharmaceutical Society of Kenya, there are about 4,000 pharmacists in Kenya, nearly 50 percent of whom are engaged in nonpharmaceutical work. Many of the pharmacy graduates have left the core industry to work in other sectors because of the limited opportunities it provides. If there were more job opportunities in the production division, coupled with a curriculum that meets industry needs, then students are likely to develop an interest in acquiring skills and seeking employment in the industrial pharmacy segment.

Survey respondents among the university faculty estimate that the production subsector provides about 10 job opportunities for pharmacy graduates per year, and even these are mainly in regulatory and quality assurance departments but not in actual production process management.

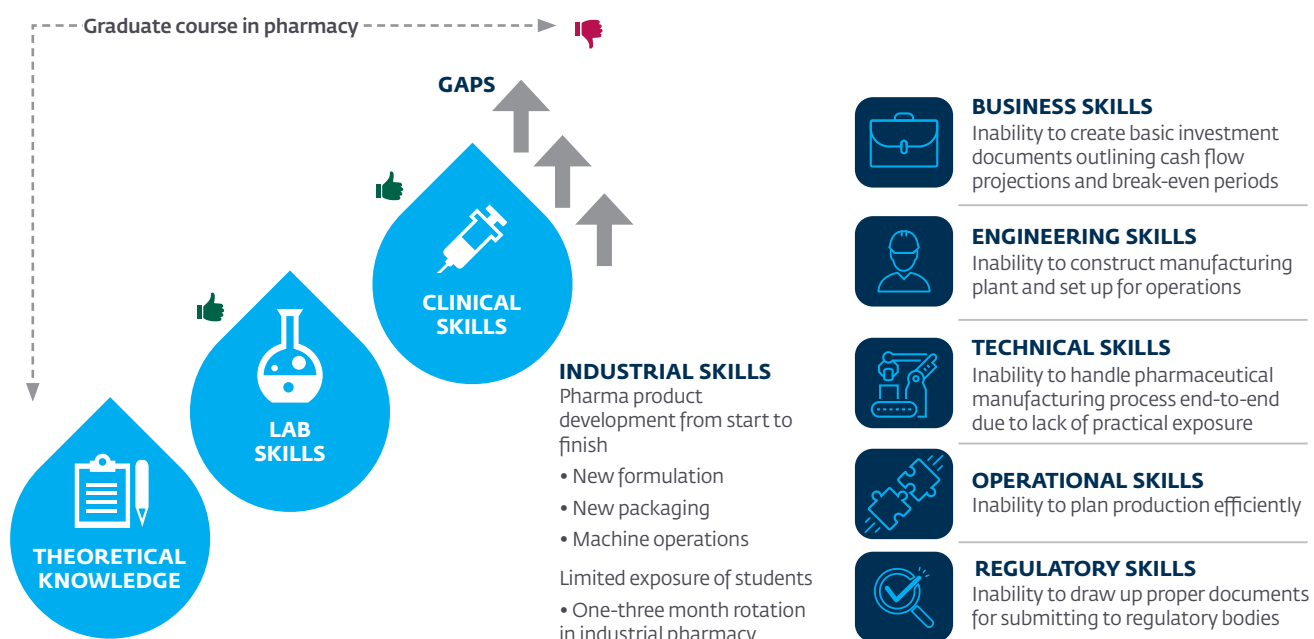
Currently, seven universities in the country offer pharmacy training, with 70 students to 120 students per batch annually entering or leaving college at the graduate level. Of these seven universities, three are new and have not had a class graduate yet. There are about 300 Bachelor of Pharmacy students joining college or graduating every year, and this number is set to rise to about 500 a year by 2021 or 2022.

Some of the human-resource-related issues identified during interviews with pharmaceutical manufacturers, academicians, and professional bodies in the country are detailed below.

Unresponsive pharmacy curriculum: The current pharmacy curriculum is too theoretical and does not effectively confer practical skills for graduates to be market/task-ready in the industry. While this weakness has been evident for years, it has not been adequately addressed, partly because, budgetary constraints have inhibited universities from reviewing and implementing an enhanced approach to learning that gives greater priority to experiential learning and mentorship in the industry. Furthermore, many of Kenya's universities do not have the requisite equipment and facilities for training students to work in the changing environment of the pharmaceutical industry. Respondents also reported a declining level of interest among students in the profession and practice of pharmacy during the internship.

The current curriculum does not equip students with adequate and relevant skills related to pharmaceutical

FIGURE 18: SKILL GAPS IN THE PHARMACEUTICAL INDUSTRY



production, new formulation development, and packaging. There is a need to review the pharmacy curriculum and provide the requisite infrastructure and faculty to implement it effectively in the country.

Limited absorption of graduates into public service: Before devolution and the creation of county governments, there was a transparent system at the national level which provided all new pharmacy graduates with the opportunity to undertake a one-year paid internship and be fully absorbed into service after completing their training and getting registered. This process has been dissolved in the wake of the transfer of most of the medical services to the 47 counties. This has undermined the former structure and practices that dealt with internship and post-internship decisions on pharmacy graduates or technologists. A gradual decline in the availability of jobs across the manufacturing subsector has also been observed. The manufacturing companies usually have two to three pharmacists per plant, and this is often only because of binding legal requirements to be certified to operate a manufacturing plant in the country. By Kenyan law, the departments or positions in manufacturing that ought to be headed by a pharmacist are Quality Assurance, Regulatory Affairs, and Production.

Small pool of skilled workforce: Firms face challenges in filling jobs from within the Kenyan market for certain roles in the industry, including quality assurance and the development of new formulations. Graduates tend to have good theoretical

understanding, but this study found that many graduates prefer to join the retail sector rather than production. Significant investments in training programs of an average of three to six months must be made to strengthen the skills of staff upon employment. This diverts limited resources, including staff time from production. Without a local pool of qualified labor, firms rely on expatriate labor mostly from the mature South Asian market, at high cost, to support new formulations development and the installation and maintenance of specialized equipment.

Recognition/accreditation of industrial pharmacy courses: Delays in categorization and certification of specialist pharmacists undermines any attempt to bridge the critical human resources gap in the pharmaceutical industry. As of February 2020, the PPB was working on a policy and process of segmented certification of categories of specialist pharmacists, including industrial pharmacy specialists.

Gap in skills mix: The pharmaceutical manufacturing/production subsector suffers from a lack of local graduates with the requisite practical skills to develop new drug formulations and to install and maintain high-end manufacturing equipment. The industry has, therefore, depended on expatriate labor to cover the skills gap in the local labor supply related to these areas. This stopgap works poorly for production entities located outside the main urban centers where foreign staff are not confident of their personal safety or access to certain amenities. Further, the companies that hire foreign labor provide very high

TABLE 5: SUMMARY OF HUMAN RESOURCES CHALLENGES

1	Lack of business and engineering skills	Many graduates in the labor pool often lack some skills, e.g. business, engineering, technical, operational, GMP, and regulatory skills.
2	High attrition rate among personnel	Firms experiencing poaching and turnover in a market where a pipeline of talent for skilled labor is not available locally.
3	Low acceptance by the pharmaceutical industry	There is a perception in the industry that graduates are inadequately prepared to work in the industry. This is also due to the fact that the Industrial Pharmacy degree by the University of Nairobi and others have taken a long time to become accepted, recognized, and certified. The PPB is in the process of giving recognition to all industrial pharmacy specialists.
4	Reliance on expatriates	Manufacturers have to rely on expatriates who are expensive, and expats are available only if the manufacturer is located close to central business districts.
5	Lack of attractiveness in the sector	There is a perception among graduates of low pay in the manufacturing subsector. Graduates therefore show low interest in the course and move to other sectors of the economy.
6	Significant investment required in training by manufacturers	Significant investments in training programs are needed, and these take an average of three to six months. This diverts limited resources such as staff time from production.
7	Lack of engagement among academia, government, and industry	There is a lack of engagement among academia, government, and industry, resulting in gaps in industry requirements and workforce expectations.
8	Lack of funding at university level	Universities lack finances to adopt training approaches that ensure graduates leave college when they are market/task-ready. Mentorship visits by students and faculty to foreign plants and international institutes for exchange visits/mentorship are not undertaken.

FIGURE 19: STAKEHOLDERS' SUGGESTIONS TO ADDRESS CHALLENGES IN HUMAN RESOURCES



remuneration to attract employees into their service, which increases these companies' overall cost of production.

Further challenges in the human resources domain are, in general, the lack of nonproduction-related skilled staff to perform supportive roles and other activities that ensure the full value chain elements and their outputs are covered. Respondents at the PPB stated that manufacturers in Kenya in general lack the capacity to undertake proper documentation to support drug registration applications or the development of standard technical documents. Respondents at the manufacturing companies, too, indicated that there is a dearth of managerial skills, including those needed to develop business cases and forecast demand. There is also a lack of ancillary engineering skills in the industry. These skills relate more to manufacturing plants using heating, ventilation, and air-conditioning equipment, and the lack of these skills can result in downtime at production facilities.

The identified human resources-related challenges are being addressed in several ways. Below is a summary of the initiatives being undertaken or under consideration by the government to increase the skilled workforce (and improve the skills mix) available to the industry.

- There is a gradual shift towards a competency-based curriculum. The pharmacy training curriculum is under review to enhance a practical, experiential learning approach.
- The PPB is developing a plan to categorize, accredit, and certify specialist courses, such as industrial pharmacy.
- The development and implementation of a pharmaceutical industry-specific training curriculum for nonpharmacy

staff, including in business development, engineering, and marketing.

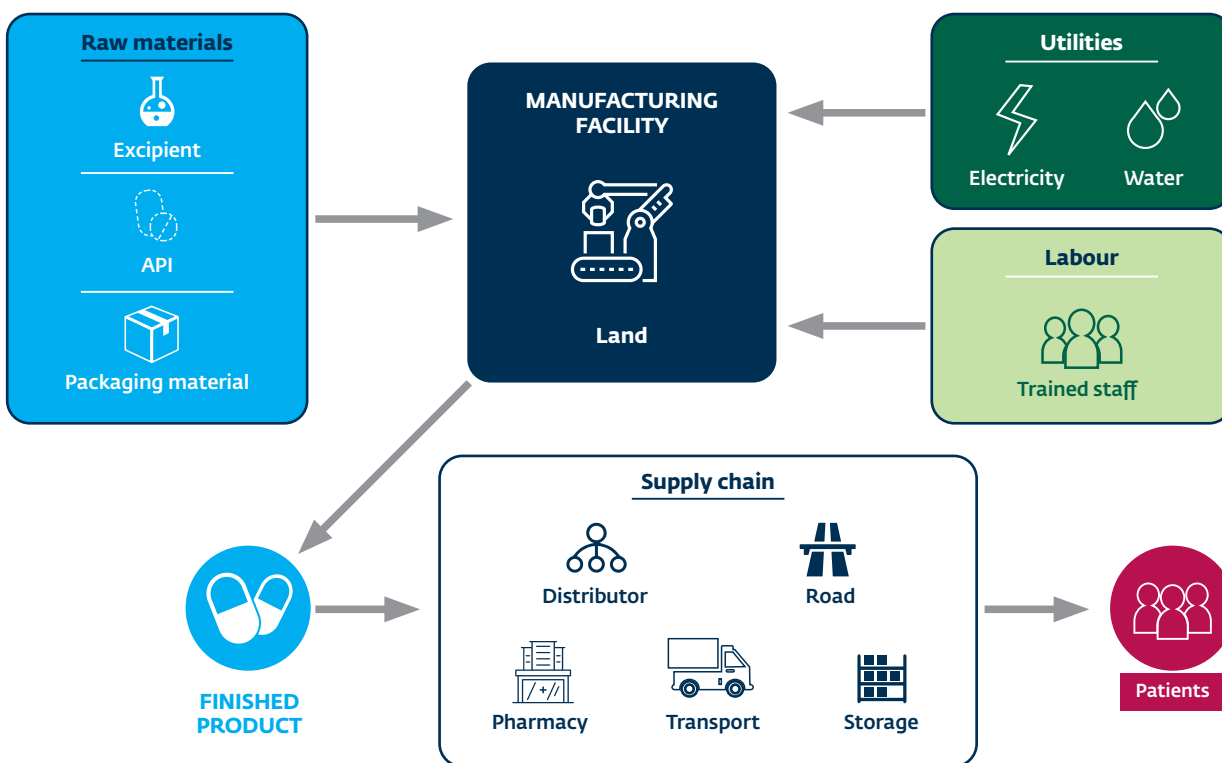
- The development of a collaborative forum to provide a regular opportunity for the industry, academia, and government to discuss issues affecting the industry. The resultant action plans would contribute to developing a specialized workforce to serve in all areas of the industry, as well as a mechanism to facilitate industry support to universities or the sponsorship of staff to undertake industry-specific courses/programs to address emerging needs.

The availability of a local skilled workforce that adequately (in terms of skills mix and number) addresses the diverse needs of the pharmaceutical industry is a prerequisite for growing product research and development, and manufacturing for both the national market and regional export market. There is, therefore, a need to develop and implement a clear National Pharmaceutical Sector Workforce Development Plan.

3.6.2 Operational landscape

The pharmaceutical manufacturing industry requires that certain critical inputs are available to support the manufacture and supply of products to markets. These include locally produced and/or inexpensive raw materials such as APIs, excipients, and packaging materials; land to construct manufacturing facilities; access to a reliable, low-cost supply of essential utilities such as water and electricity; skilled labor; a responsive distribution system; and low-cost capital to finance the procurement and upgrading of manufacturing-related infrastructure and equipment.

FIGURE 20: KEY REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURING



The survey identified several factors that affect the operations and performance of the pharmaceutical manufacturing industry in Kenya. These are elaborated on in Figure 20.

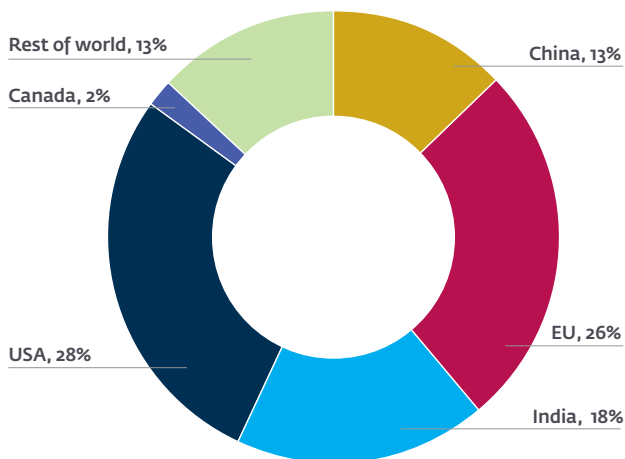
3.6.2.1 Availability of raw materials

The availability of raw materials for pharmaceutical manufacturing in Kenya is limited. The country is heavily reliant on imported items. About 95% of APIs and excipients are imported due to lack of local API manufacturing capacity and the high cost of electricity. Most APIs come from and India. China is the leading exporter of APIs to pharmaceutical manufacturers worldwide. Several factors, such as cheap labor, vast economies of scale, a robust chemical industry, low cost of capital, and government funding and other incentives,⁸⁵ support China's global dominance in API production and supply.

According to a 2009 World Bank report, Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines, API manufacturing shifted to China and India due to the low cost of production in these countries. A western API manufacturer has an average wage index of 100, whereas this index is 8 for China and 10 for India. Electricity, coal, and water costs are also lower in China, and Chinese manufacturers benefit from lower shipping and transaction costs for raw materials.

Kenya has not invested much in the local development, production, and supply of all APIs and excipients because of the substantial initial investment required in equipment and human resources, and limited local demand.⁸⁶

FIGURE 21: PERCENTAGE OF API MANUFACTURING FACILITIES BY COUNTRY OR REGION, 2019



Kenya has some locally available raw materials that are used as excipients in manufacturing, including maize starch, refined sugar, glucose syrup, rectified spirit ethanol, sodium chloride, gum, acacia, crushed capsicum, and honey. In general, pharmaceutical manufacturers lack a reliable supply of local raw materials and sufficient control over their quality. The supply is often erratic, with long lead times, which hampers production. This is particularly challenging for manufacturers that are unable to import in bulk.⁸⁷

Importing raw materials involves similar risks, including long lead times, variable product quality, and delays in customs and clearance. To ensure adequate supply, many companies procure and hold stock to cover six months. This not only leads to high inventory holding costs but higher risks of loss or damage to a large quantity of goods in transit. Industry players reported that the clearance process at airports takes up to one month because of slow inspection processes. Most supply chain disruptions and delays related to locally manufactured products have been linked to the challenges of acquiring raw materials.

For Kenya to become a pharmaceutical manufacturing hub, it needs to reduce its dependence on imported APIs and excipients. The country should aim to provide at least 50 percent of the demand for raw materials from locally produced APIs and excipients by 2030.

Another challenge is the inconsistent quality of locally produced packaging materials. In addition, local packaging can be more expensive than imported packaging because of VAT and high electricity costs to manufacture the packaging. Import duty and VAT on packaging is unclear. Manufacturers do not have to pay any duty on the import of packaging material as it is considered a raw material. However, when packaging is sourced from local suppliers, manufacturers have to pay 16 percent VAT. The VAT can be reclaimed from the government, but it is a slow process; it can take years to receive remittances.

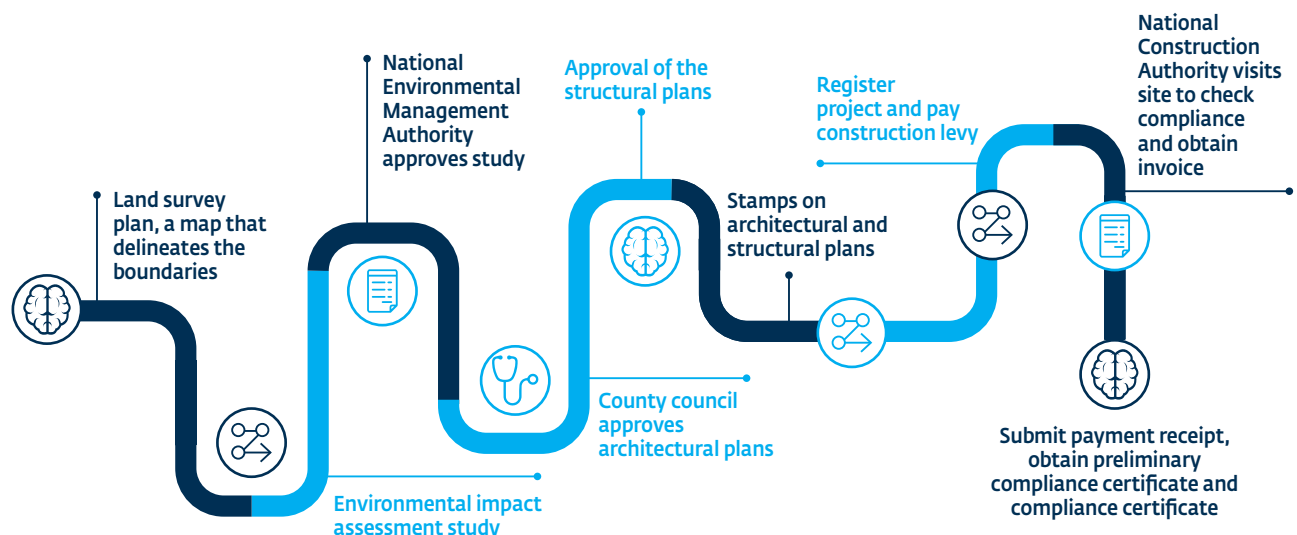
To promote the local packaging industry, the reimbursement process needs to be reviewed and amended to enable faster remittances. This will lead to reduced capital costs associated with packaging material and encourage local manufacturers to source packaging from local suppliers.

3.6.2.2 Manufacturing facilities

3.6.2.2.1 Land acquisition and construction permits

Owning land is critical for investors who want to build custom-designed manufacturing facilities. However, obtaining the title deed (which is a requirement for owning land) can be an uncertain and contentious issue in Kenya.⁸⁸ There are reports of firms having to change their business location due to a lack of proper title to land. Respondents described the availability of land as a moderate challenge in

FIGURE 22: THE PROCESS OF OBTAINING A CONSTRUCTION PERMIT AND STANDARD TIMELINES



1 day	5 days	-	-	45 days	1 day	10 days	7 days	-	-
Land survey plan	Project report by environmental expert	Environmental Impact Assessment study	Approval of the environmental impact study from NEMA	Approval of architectural plans	Approval of structural plans	Stamps on architectural and structural plans	Project registration and payment of levy	On-site visit by NCA	Submit payment receipt and obtain preliminary certificate and compliance certificate



Kenya, with the cost of land and proof of ownership being the main roadblocks. The process of acquiring land can take up to three months if all legal processes and procedures, and the stipulated payment periods (payment of a deposit and the balance of the contract amount in 90 days) are followed. Longer transaction durations are a challenge for firms.

According to the Doing Business Report 2020, Kenya has taken several steps to improve the process of registering property and getting permits. The country has:

- **Improved the transparency of the construction permit process** by placing building permit requirements online and by reducing the permit fee.
 - Kenya was ranked 104th on this parameter in 2020, up 19 positions from 2019.
 - The total cost of acquiring a construction permit was reduced from 5 percent of the warehouse value in 2019 to 2.8 percent in 2020.
- **Made it easier to register property** by reducing the time it takes to get a search done and process a title.
 - Registering property takes 43.5 days in 2020, down from 49 days in 2019.
 - However, an additional requirement to generate a pay slip was introduced.

Another challenge is that all foreign investors are subject to a limited 99-year lease on land (and consideration is given for renewal on application), which increases the risk of expropriation of property on expiry of the lease. Corruption and risk of loss of money during land purchase remain concerns for foreigners wishing to set up industry in Kenya.^{89,90,91}

A construction permit gives the permit holder permission to erect specific structures on designated land. The time it

takes to obtain this permit is determined by the intended use of the structure, complexity of the planned construction, and location. According to the KenInvest webpage on eRegulation, it takes between 116 days and 176 days, and 32 documents to obtain a construction permit in Kenya. While this time period compares well with other regional markets, Kenya has a much higher number of procedures than its peer markets. Obtaining a construction permit costs about 4.7 percent of the value of the planned building, which is competitive against the 8.8 percent charged on average in Sub-Saharan Africa. Some respondents reported that engineering skills for specialized construction plants are lacking, and manufacturers fill this gap by bringing in expatriates to help.

3.6.2.2.2 Availability of equipment and spare parts

Pharmaceutical manufacturing requires specific equipment for the various stages of the production process. These include mixers, liquid filling, and tableting machines. Kenya lacks the capabilities to manufacture some of the critical equipment, as it does not have a well-developed specialized tooling industry or a pool of skilled people. Therefore, all pharmaceutical manufacturing equipment is imported at a very high cost. Moreover, when an installed machine breaks down, it takes weeks for spare parts to arrive, resulting in extended downtime and lost production. The engineers or technicians who service and repair the equipment and provide training in the local pharmaceutical industry have to come from abroad. A respondent in one firm said that they even have to seek calibration services for specialized equipment from abroad, or the equipment is shipped out to an expert if they cannot visit the site.

Unless local capacity is developed, given these circumstances, manufacturers may not easily expand their

operations to produce large volumes of pharmaceuticals or to become more vertically integrated. There is, therefore, a need to encourage the development of local expertise and a cluster of companies to support the local pharmaceutical manufacturing industry in Kenya.

3.6.2.3 Utilities

3.6.2.3.1 Electricity

Access to a reliable and low-cost power supply is crucial to manufacturing. High power tariffs increase the cost of production, and frequent outages undermine productivity and cause damage to equipment and products in-process.

Kenya has invested significantly in power generation, but the reliability of the national power grid system and especially the reticulation of electricity remains a key challenge.

Manufacturers contend with high electricity costs,⁹² and power outages and fluctuations in voltage are common in the country. Industry respondents indicated that the frequent power outages they experience result in machine downtimes that reduce productivity, while voltage fluctuations damage sensitive equipment, especially automatic machines with a program logic controller. To address these power challenges, many firms have invested in secondary power generation capacity, leading to an increase in their overall operational costs. Manufacturers also need to invest in additional equipment such as voltage stabilizers.

The average cost of commercial electricity in selected countries is depicted in Table 6.⁹³

In Kenya, multiple surcharges are applied on the base tariff for electricity consumption such as a fuel cost charge, foreign exchange rate fluctuation adjustment, inflation adjustment, water resources management authority levy, energy regulatory commission levy, rural enterprise program levy, power factor surcharge, and VAT.⁹⁴

TABLE 6: COMMERCIAL PRICE OF ELECTRICITY IN DIFFERENT COUNTRIES

No.	Country	Commercial electricity prices (\$ per kWh)
1	Kenya	0.19
2	United Kingdom	0.19
3	Uganda	0.16
4	United States	0.11
5	Bangladesh	0.10
6	Tanzania	0.10
7	China	0.09
8	South Africa	0.05
9	Ethiopia	0.02

The government is exploring several ways to bring down power costs in SEZs by limiting the distribution tariffs and using other nonconventional sources of energy. For example, the 1,000-acre SEZ being developed in Naivasha (in Nakuru County) will access electricity from a nearby geothermal plant at a cost of \$0.05 per kWh.⁹⁵

In addition, with effect from December 2017, the government has designated off-peak hours in a bid to have to have a 24-hour economy as follows:

- Weekdays: 12 AM to 6 AM and 10 PM to 12 AM.
- Saturdays and public holidays: 12 AM to 8 AM and 2 PM to 12 AM.
- Sundays: all day.

During off-peak hours, the base tariff rate is halved for commercial electricity consumption. To spur investments in industry, the Kenyan government is assessing the quality of power supply and reviewing the cost of electricity with a view to ensuring competitive rates. Under consideration, too, is the use of differentiated tariffs and locating SEZs close to power generation sites.

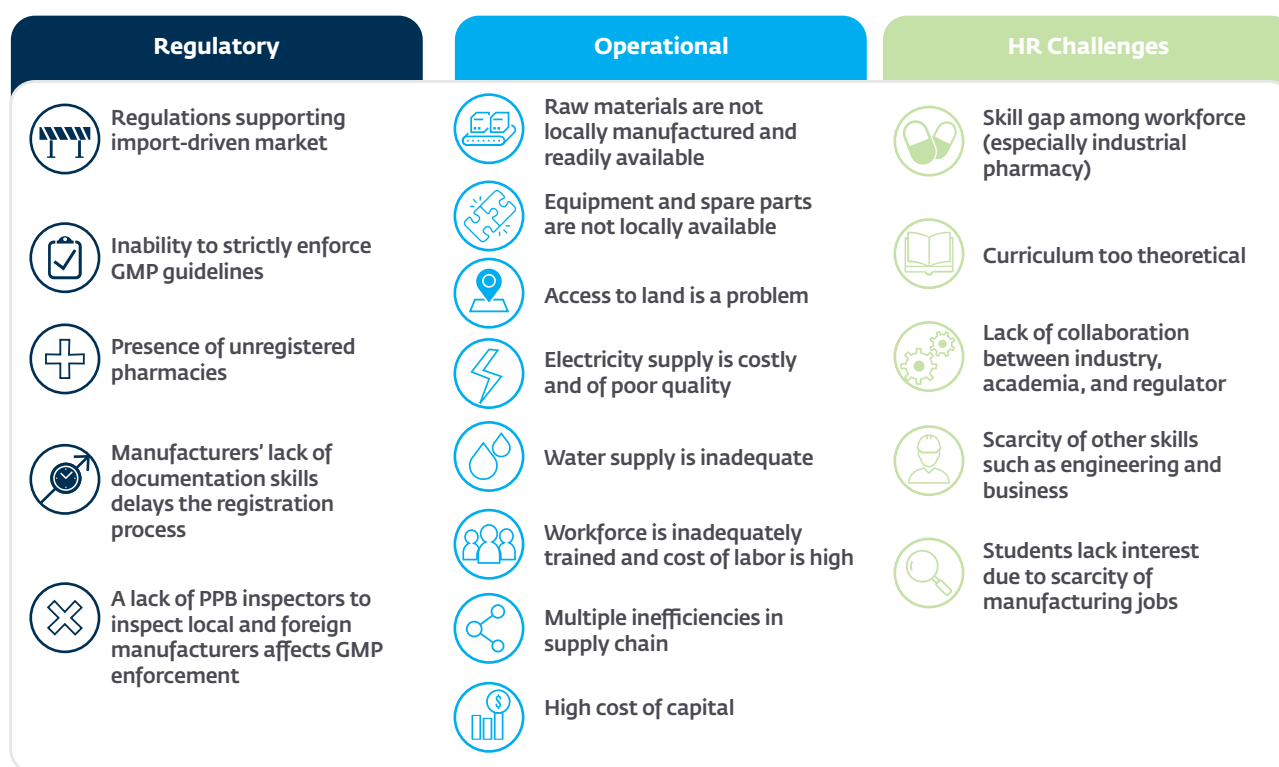
3.6.2.3.2 Water

Water is a key input in most manufacturing processes. As such, access to reliable, good-quality water is an important consideration for investors who have invested or wish to invest in pharmaceutical manufacturing. The gap between water supply and demand in Kenya is increasing due to population growth and the effects of climate change. Diminishing supply has resulted in water rationing in urban centers, especially Nairobi. The volume of available renewable water in Kenya is an estimated 647 cubic meters per capita, against a United Nations recommended minimum of 1,000 cubic meters.⁹⁶

Nairobi, which is the central hub for manufacturing activity, suffers from a 25 percent deficit in water supply. If no sustainable action is taken, this is projected to rise to about 60 percent by 2035.⁹⁷ In 2018, only about 57 percent of households in the country had access to a potable or piped water supply. The demand for industrial water supply is expected to grow by 125 percent between 2014 and 2030.

The supply of water in Kenya, and especially Nairobi, is unreliable and inadequate for industrial purposes. Constant rationing means that supply may be available only for some days of the week in Nairobi. In addition, the quality of water from the public supply utilities is not appropriate for industrial use. As a result, many manufacturers have invested in boreholes to ensure a continuous water supply, and many have installed water treatment plants to ensure they meet the pharmaceutical product's production standard.

FIGURE 23: SUMMARY OF CHALLENGES AFFECTING INDUSTRY PLAYERS



A respondent from one multinational manufacturer situated in an export processing zone is contractually assured by site developers of piped water supply but is considering sinking a borehole. Many investors view borehole development as a one-time cost that guarantees them a reliable source of water.

3.6.2.4 The cost of capital

Setting up or upgrading a pharmaceutical manufacturing facility is costly. Those without adequate capital seek financing from venture capital markets or the banking industry. Business plans need to show the viability and potential performance of the entity. On evaluation, those approved for funding may be required to deposit certain assets as collateral for the loans. Although commercial banks are willing to lend to manufacturers, they sometimes require a significantly high value of collateral compared to the loan amount, which affects the accessibility of the loan cash for any plant upgrades. The interest rates charged in Kenya are generally higher than in other nations. For example, the interest charged on loans in Kenya is about 5 percentage points higher than in India and China.

A recent change in regulations by the government has helped increase liquidity and accessibility of loans. From 2016, interest rates were capped at 4 percent above the Central Bank lending rate, and banks were reluctant to lend.⁹⁸ This was abolished in November 2019.⁹⁹ More people

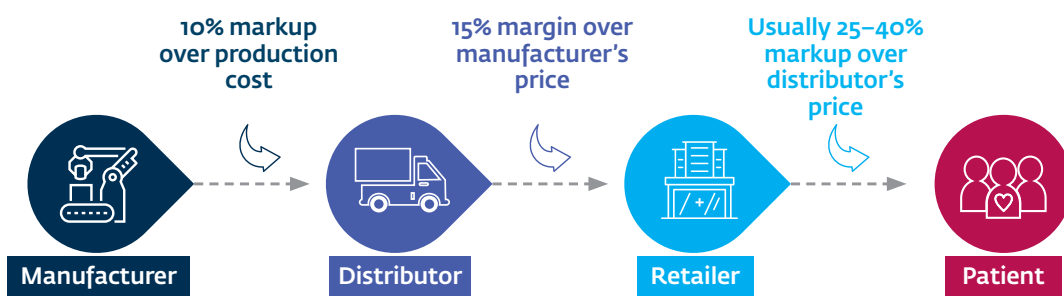
and businesses are now able to access loans, but at a higher interest rate.

To improve financing opportunities for businesses in the pharmaceutical sector, trade associations and pharmaceutical manufacturers could reach out to the banking industry with proposals for consideration to spur mutually rewarding investments. To get loans at a lower interest rate, they will need to convince banking and financial institutions that pharmaceutical investments are low risk.

3.7 The market pricing landscape

Manufacturers in the pharmaceutical industry determine their base unit prices for any commodities they produce based on the aggregated and proportionate allocation of costs of all inputs (equipment, materials, labor, management, demand creation, and marketing) and on profit margins to support further investments and create shareholder value. Another consideration is the prevailing market environment, especially if the product has a close competitor in formulation choice or efficacy. If the product is unique, with no alternative or competitor in its class, the company can be aggressive in pricing if the market accepts it. If prices are set too high in a low-resource environment, sales volumes may not be realized, leading to failure of the product. However, a resource-rich market environment can accommodate a low-volume, high-price product if the

FIGURE 24: PRICING NORMS AND MARKUP STRUCTURE



product is unique and does not have competitors supported by more capable peer companies in the sector.

A WHO report and the PPB Magazine confirm that the country does not have a price control for pharmaceuticals.¹⁰⁰ Kenya has left the prices of pharmaceutical products to be dictated primarily by market forces. However, suggested indicative price ceilings are set to ensure the survival of the various players in the value chain. The legacy tariff structure in the industry suggests that distributors add product markups of 15 percent on the manufacturer's base unit price to arrive at the trade price that the retail pharmacies and hospitals pay. The retail pharmacy should add 33 percent to the trade price to determine the retail price to the final consumer. These suggested rates are not enforced, and the players in the value chain negotiate prices, give discounts, set prices depending on market data and sentiment on what the prevailing market is willing to pay, and then make adjustments regularly as appropriate. Some stakeholders in the health sector (especially politicians) have been advocating for government-sanctioned price controls to help expand access to health products in the country.

The diagnostic survey aimed to identify the key determinants of prices of pharmaceutical products. The results are elaborated below.

3.7.1 Product pricing

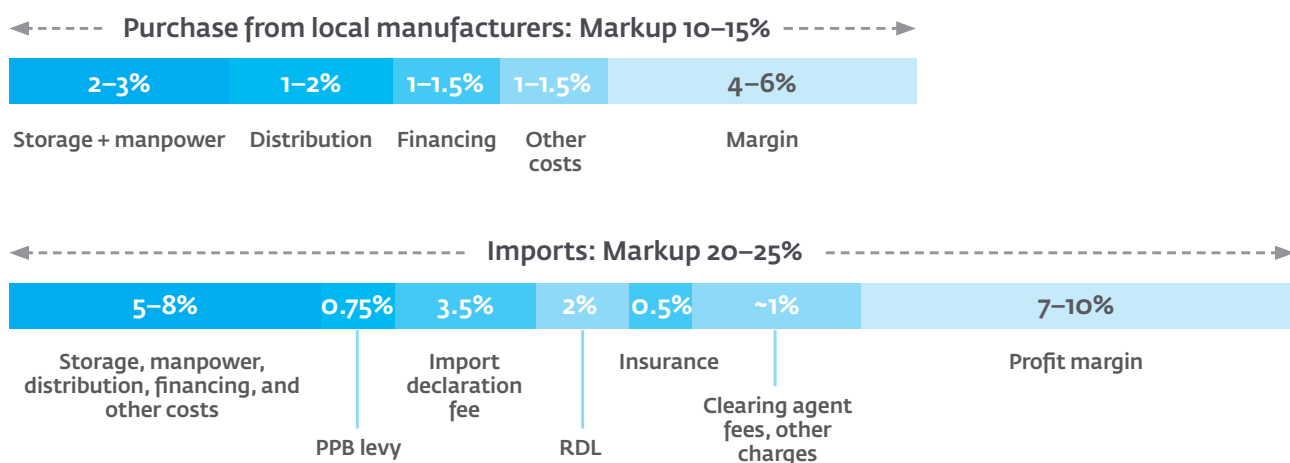
As Kenya does not have a clear formal price control policy for pharmaceutical products, pricing (base unit costs and markups) is largely dependent on the number of intermediaries involved in the supply chain, and what consumers are willing to pay. There are multiple markups at different stages of the supply chain, escalating as the chain approaches the consumer.

Manufacturers sell their products to distributors at a fixed price. They also sell directly to some strategic customers (hospitals and large institutional clinics) to lower the costs barrier and ensure their products are not substituted due to cost or lack of responsive supply by the distributors. Distributors' markups vary by the scale of their operations, purchase sources, and service offerings. Distributors use this leverage to their advantage and exploit information asymmetries in the market to enjoy higher markups and

FIGURE 25: SUMMARY OF DETERMINANTS OF PRICE MARKUP ON PHARMACEUTICAL PRODUCTS

Scale of operations	The larger the distributor's business, the lower the markup that is added to products.
Size of business or product	The larger the size of the established market for a product, the lower the markup that is added to that product. Products in the early stages after introduction are sold at higher markup.
Price of the product	The higher the base unit price of the product, the lower the markup added to that product.
Therapy area of the product	Some therapy areas like oncology, antimalarials, and antiretrovirals are sold at lower markup.
Services provided	Additional services provided by the distributor (like import or sales and marketing support) are charged separately and add to the markup.
Location of the pharmacy	Markups in pharmacies are set based on patient affordability , which is directly related to the locality of the pharmacy. Low-end pharmacies tend to charge higher mark-ups while the pricing policies of high-end pharmacies are standardized.

FIGURE 26: COST AND MARGINS FOR A LARGE DISTRIBUTOR



profits overall. Currently, the Kenyan pharmaceutical industry landscape has very stiff competition, with companies fighting aggressively for market share. This has resulted in some players discounting products heavily.

The study found that discounts of up to 30 percent are not uncommon. Furthermore, products that are nearing their expiry are even more aggressively discounted to attract customers. This has created the perception that low-price products are lower quality and that companies are cutting corners to make a profit.

3.7.2 The main determinants of markups by distributors and retailers

Several factors influence drug prices and availability. These include the business location and the associated costs of workspace ownership or rental, regulatory and trade licenses, type and size of business (distribution or retail pharmacy), whether the product is an innovation or a generic, the product's therapeutic category, product formulation type (tablet or liquid), and whether it is locally manufactured or imported. Markup and distributor margins depend on the scale of their operations (larger scale may allow for lower markups and profit on high-volume sales) and type of product (with a lower margin on generics).

The key cost drivers in the distribution and retail business are costs for rental and human resources. The price of medicines to end-users is partly determined by the number of intermediaries and prices paid by retailers. Due to lax regulatory practices and lack of robust enforcement of national guidelines (because of the current limited inspectorate capacity at the PPB), distributors in Kenya have been hurt by competition from those engaged in parallel imports and sale of contraband products. Distributors need to invest in registering and marketing the product.

The retail market in Kenya is fragmented. There are many unregistered retail pharmacies that are not licensed by the PPB.

Generally, retailers claim to apply markups of 20 percent to 45 percent on product cost. However, it is evident from the survey respondents that, in some instances, much higher markups are being applied. In general, retailers mark up cost prices by an estimated 20 percent to 45 percent to make a profit of 15 percent to 20 percent, and to cover operational costs with the remaining 10 percent to 15 percent. The survey results indicate great variations in markups applied. In Kenya, retail pharmacies face the following challenges in their operations:

- **Lack of transparency in product pricing:** Retailers have minimal access to information on the involvement or influence of multiple intermediaries in the value chain.
- **Limited credit:** The inability of smaller pharmacies to access credit from distributors and wholesalers impacts their business and financial performance.
- **Varying product quality:** The quality of commodities is mostly assumed, and retailers cannot be completely sure of product efficacy and safety.
- **Reliable demand data:** Limited access to data on national purchasing trends and past consumption affect appropriate planning for procurements.

There is a need for government and business associations to meet regularly to jointly identify the challenges that stakeholders face and implement solutions that are mutually beneficial. While stopping parallel imports and contraband items can improve the quality of available commodities, aggressive regulation of drug prices could

undermine new investments in the country by citizens or foreign players seeking to introduce innovator drugs with a faster return on investment. This highlights the need for consultation before changing or implementing policies.

3.7.3 Market pricing survey

To understand the key drivers and variations in the price of products to consumers, retailer markups, and availability of key drugs in the market, a market pricing survey was conducted in three counties in Kenya: Kisumu, Nairobi, and Mombasa. The results are discussed below.

3.7.3.1 Selection of medicines

Three categories of drugs were selected for inclusion in the survey, as summarized in Table 7.

Within each category, higher volume products were purposely chosen (to ensure that pharmacies were more likely to have such products in stock), and the range had

TABLE 7: TYPE OF DRUG CATEGORIES SAMPLED AND SURVEYED

Type of drug	Description ¹⁰¹
Category 1	High priority drugs, including drugs from Kenya's 2016 key essential medicines list and those currently funded by donors
Category 2	Drugs that are exclusively imported
Category 3	Drug formulations that are manufactured locally and imported

to have different formulations to assess if the price and availability vary by formulation.

3.7.3.2 Drug availability

Category 1 drugs

The availability of Category 1 drugs ranged from 13 percent for Dolutegravir + Lamivudine + Abacavir, to 93 percent

FIGURE 27: AVAILABILITY OF CATEGORY 1 DRUGS

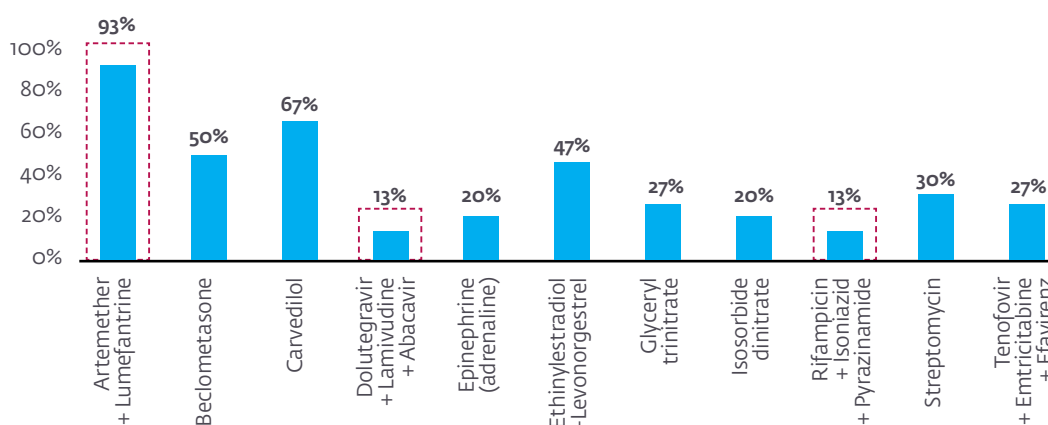
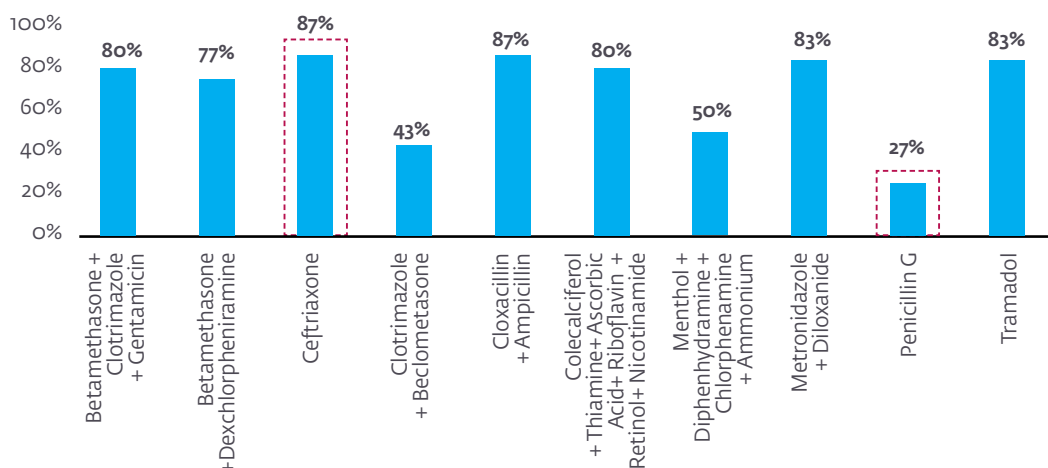


FIGURE 28: AVAILABILITY OF CATEGORY 2 DRUGS



for Artemether + Lumefantrine. Category 1 drugs are less commonly available in private pharmacies than in the other categories, primarily because they are donor-funded and largely dispensed to clients through public facility pharmacies. It was important to survey their availability and pricing because those wishing to target the production and supply of these products need to understand the prevailing context in Kenya.

Category 2 drugs

Availability of Category 2 drugs ranged from 27 percent for Penicillin G. to 87 percent for Ceftriaxone.

Category 3 drugs

The availability of Category 3 drugs ranged from 93 percent

for Paracetamol to 20 percent for Tetracycline. Four locally manufactured drugs had higher availability compared to imported drugs. The drugs sampled and surveyed under Category 3 included Metronidazole, Paracetamol, Sulfamethoxazole + Trimethoprim, and Tetracycline. Overall, Category 3 drugs were found to be proportionately more available regardless of drug type.

3.7.3.3 Variations in the drug prices to the consumer

Category 1 drugs

Among the surveyed Category 1 drugs, the maximum price differential was observed for the HIV drug combination Tenofovir disoproxil + Emtricitabine + Efavirenz formulation at 9,000 Kenyan shillings.

FIGURE 29: AVAILABILITY OF CATEGORY 3 DRUGS

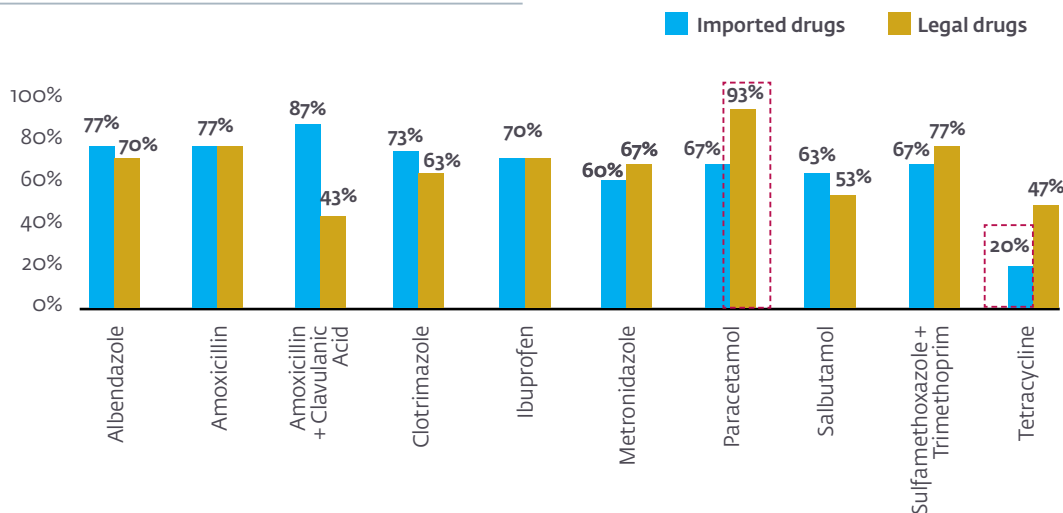


FIGURE 30: MAXIMUM VS MINIMUM PRICE (KENYAN SHILLINGS) OF CATEGORY 1 DRUGS

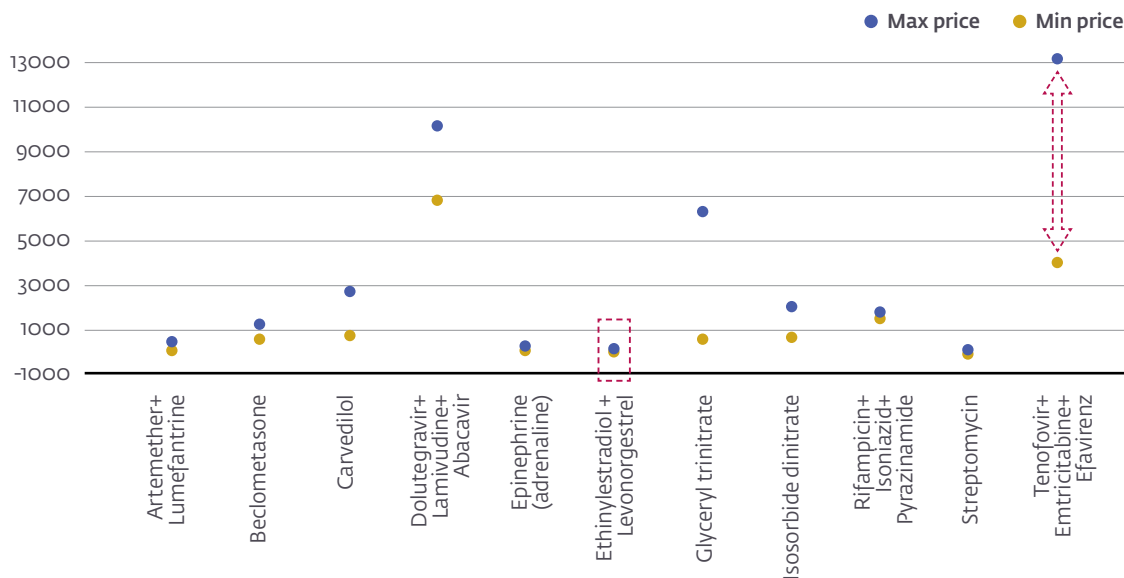
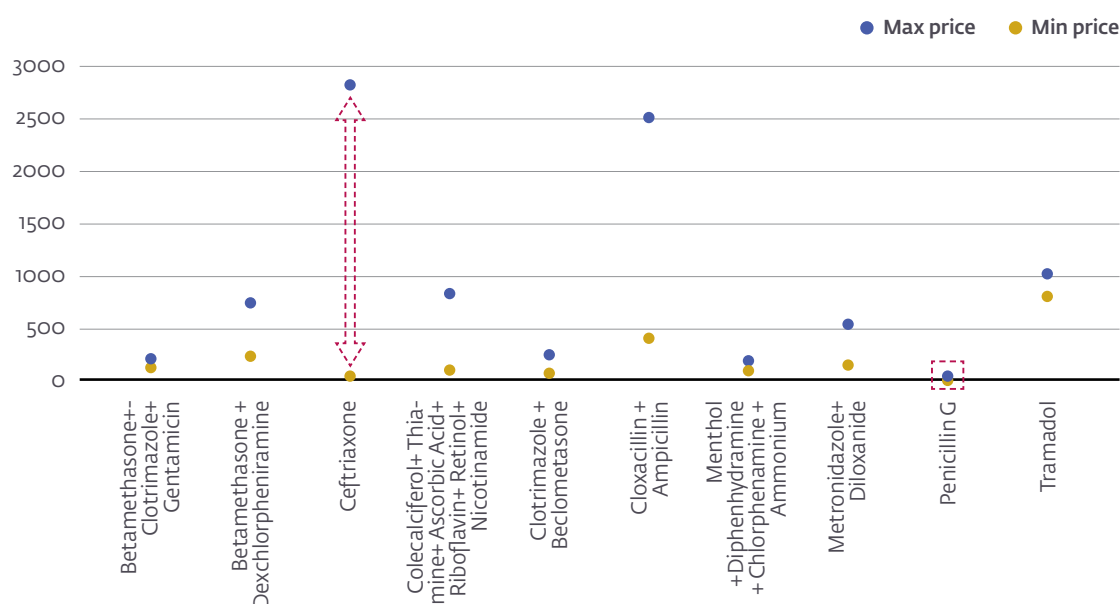


FIGURE 31: MAXIMUM VS MINIMUM PRICE (KENYAN SHILLINGS) OF CATEGORY 2 DRUGS



Category 2 drugs

Among the surveyed Category 2 drugs, the maximum price differential was over 2,500 Kenyan shillings for Ceftriaxone.

Category 3 drugs

Among the Category 3 drugs imported into the country, the maximum price differentials were over 1,000 Kenyan shillings for Amoxicillin and Ibuprofen. Amoxicillin by GlaxoSmithKline was being sold at 3,200 Kenyan shillings in Mombasa, compared to 300 Kenyan shillings in Nairobi. Ibuprofen by Leben Lab sold at 2,000 Kenyan shillings in Kisumu, compared to 120 Kenyan shillings for the Flamingo brand in Nairobi. A minimum price differential of 200 Kenyan shillings was observed for both Albendazole and Tetracycline.

Among the Category 3 drugs produced by local manufactures, the maximum price differential observed was for Tetracycline at over 3,000 Kenyan shillings, followed by Amoxicillin and Ibuprofen, with a differential of over 2,000 Kenyan shillings. Tetracycline by Lab Allied was being sold at 5,000 Kenyan shillings, with the lowest-priced local drug by Dawa being sold at 1,800 Kenyan shillings.

These prices were significantly higher than for comparable imported products, which fell in the range of 1,400 to 1,600 Kenyan shillings. Amoxicillin was being sold by GlaxoSmithKline at 3,000 Kenyan shillings, while the Dawa and Mediselin brands sold at 400 Kenyan shillings in Nairobi and Kisumu, respectively. The lowest price difference observed was for Salbutamol, which sold at between

100 Kenyan shillings and 200 Kenyan shillings in all three counties. It should be noted that for local drugs there is a higher variation in the lowest-priced drug and the highest-priced drug.

To promote consumption of locally manufactured drugs, KEMSA gives a 15 percent price preference to local manufacturers over manufacturers in other countries.

3.7.3.4 Overall variations by county

It was evident from the survey data that Mombasa had the highest proportion of all drug categories available at 69 percent, followed by Nairobi at 68 percent. Median markup varied by county, and Mombasa again had the highest at 74 percent. The highest markup, at 733 percent, was observed in Mombasa and the lowest, at 3 percent, was observed in Nairobi.

3.7.3.5 Drug availability and markup variation by pharmacy type

Medium-end pharmacies had the highest proportion of the drugs available at 73 percent for all three categories of drugs. The drugs with 100 percent availability included Clotrimazole + Beclomethasone, and Artemether + Lumefantrine. Low-end clinics had the fewest drugs available.

Medium-end pharmacies had the highest markups at 733 percent for cholecalciferol + Thiamine + Ascorbic Acid + Riboflavin + Retinol + Nicotinamide. The lowest markup was 3 percent for the Beclomethasone dipropionate inhaler (EML: essential medicines list) at high-end pharmacies.

TABLE 8: MAXIMUM VS MINIMUM PRICES (IN KENYAN SHILLINGS) FOR CATEGORY 3 DRUGS

Category 3 drugs	Imported drugs			Local drugs		
Drug Name	Max drug price	Min drug price	Variation in drug prices	Max drug price	Min drug price	Variation in drug prices
Albendazole	250	50	400%	280	15	1,767%
Amoxicillin	3,200	300	967%	3,000	400	650%
Amoxicillin + Clavulanic Acid	800	190	321%	400	32	1,150%
Clotrimazole	310	70	343%	600	50	1,100%
Ibuprofen	2,000	120	1,567%	2,000	100	1,900%
Metronidazole	1,500	500	200%	1,050	150	600%
Paracetamol	750	500	50%	1,000	70	1,329%
Salbutamol	500			200	100	100%
Sulfamethoxazole + Trimethoprim	1,300			650	13	4,900%
Tetracycline	1,600	1400	14%	5,000	1,800	178%

FIGURE 32: AVAILABILITY OF ALL DRUGS BY COUNTY

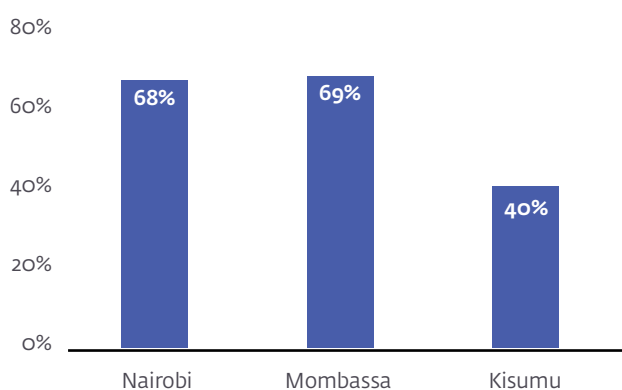
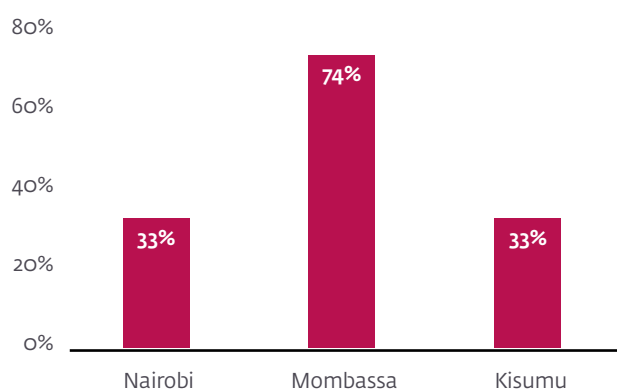


FIGURE 33: MEDIAN MARKUP ON DRUGS BY COUNTY



It was evident from the survey data that Mombassa had the highest proportion of all drug categories available at 69 percent, followed by Nairobi at 68 percent. Median markup varied by county, and Mombassa again had the highest at 74 percent.

FIGURE 34: DRUG AVAILABILITY AT TYPE OF PHARMACY

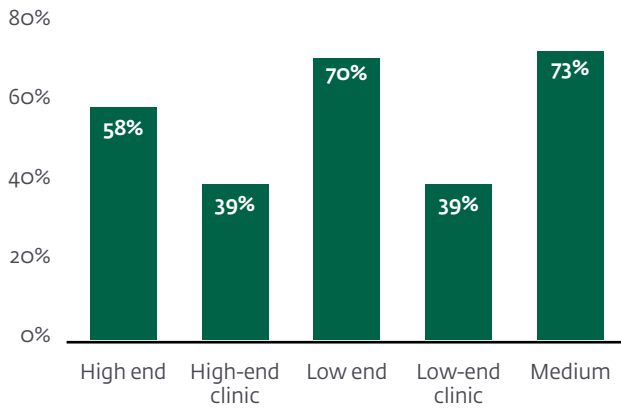
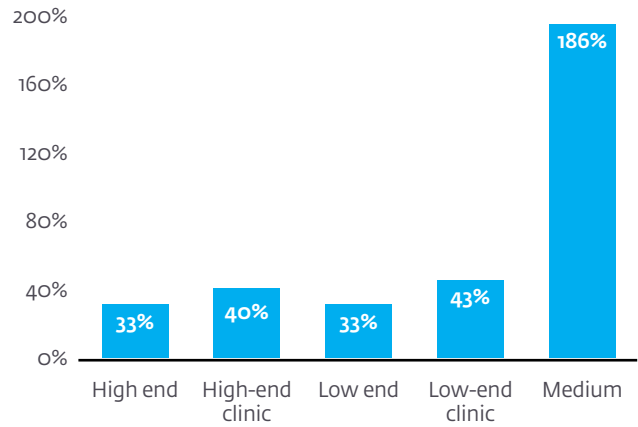


FIGURE 35: MEDIAN MARKUP BY TYPE OF PHARMACY



In summary, the results of the market pricing survey largely indicate the lack of a predictable approach to product pricing in Kenya. The markups vary by region, among and within product categories, size, and type of business, and by whom or where the product is manufactured. The pricing decisions made by the players in the Kenyan market are not just predicated on traditional, predictable features like the cost of inputs, marketing efforts, and logistics, but apparently also on information asymmetry and market sentiments.

3.8 The pharmaceutical marketplace and dominant players

3.8.1 The pharmaceutical marketplace and market share

The pharmaceutical market space is dominated by multinational companies in terms of value. The IQVIA pharmaceutical sales data, which covers about 88 percent of the private retail market, confirms this. In terms of

volume, the local pharmaceutical players have an equal market share. While multinational companies dominate the private sector retail market, local manufacturers have been increasing their reach, with three local companies among the top 15 pharmaceutical players by sales value.

Figure 36 shows the private sector retail market share of local versus multinational companies. The graph on the left shows the split in terms of value, while the graph on the right shows the split in terms of volume. Each column represents the moving annual turnover (MAT), with MAT 2017 covering September 2016 to August 2017; MAT 2018 covering September 2017 to August 2018; and MAT 2019 covering September 2018 to August 2019.

One of the key local players, Universal Corporation Limited, is not on the list, as it generates revenue from channels of distribution other than just the private retail sector. A significant share of its revenue comes from exports.¹⁰¹

FIGURE 36: KENYA PRIVATE SECTOR RETAIL MARKET SPLIT BY TYPE OF PLAYER

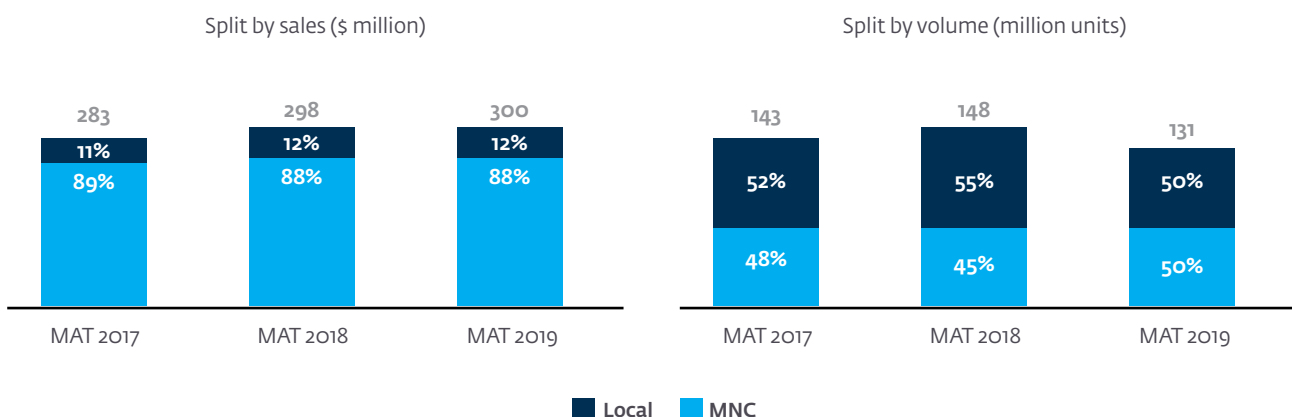


TABLE 9: TOP 15 PHARMACEUTICAL PLAYERS IN KENYA, BY SALES AND MARKET SHARE

Rank	Corporation Name	MNC/ Local	2019 Sales (US\$)	2019 MS (%)	2017-2019 CAGR (%)	PPG (MAT 08'18-'19)
1	GlaxoSmithKline (Pharma)	MNC	32.4	10.8%	-0.6%	-2.9%
2	Pfizer	MNC	15.7	5.2%	5.9%	0.6%
3	Dawa	Local	15.4	5.1%	10.9%	-4.2%
4	GlaxoSmithKline (Consumer Health)	MNC	12.6	4.2%	13.5%	14.7%
5	Glenmark	MNC	11.7	3.9%	20.8%	14.3%
6	Sanofi	MNC	11.7	3.9%	4.0%	5.2%
7	Cosmos	Local	11.2	3.7%	27.7%	10.1%
8	Novartis	MNC	11.1	3.7%	-0.6%	-3.8%
9	Roche	MNC	9.9	3.3%	8.4%	1.2%
10	Getz Pharma	MNC	9.5	3.2%	17.6%	10.9%
11	AstraZeneca	MNC	8.9	3.0%	-4.7%	-15.0%
12	Medisel Kenya	Local	7.9	2.6%	-12.2%	-9.3%
13	Merck Sharp and Dohme	MNC	7.5	2.5%	-7.2%	-12.8%
14	Cipla	MNC	7.1	2.4%	-16.8%	-22.4%
15	Bayer	MNC	6.8	2.3%	3.8%	3.8%
16	Others		120.7			

However, it sells both Cotrimoxazole and Antidiabetic medicines to MEDS. The company has a great reputation for the quality of its products in Kenya, but this also makes its products more expensive and less competitive than those of other local pharmaceutical manufacturers.

The Anatomical Therapeutic Classification (ATC) is a drug classification system that classifies drugs according to the organ or system on which they act. ATC3 refers to the pharmacological subgroup. In terms of ATC3 classes, antibiotics represent the largest therapy area in the private

FIGURE 37: ATC 3 COMPOUND ANNUAL GROWTH RATE VS THE PPG RATE CHART

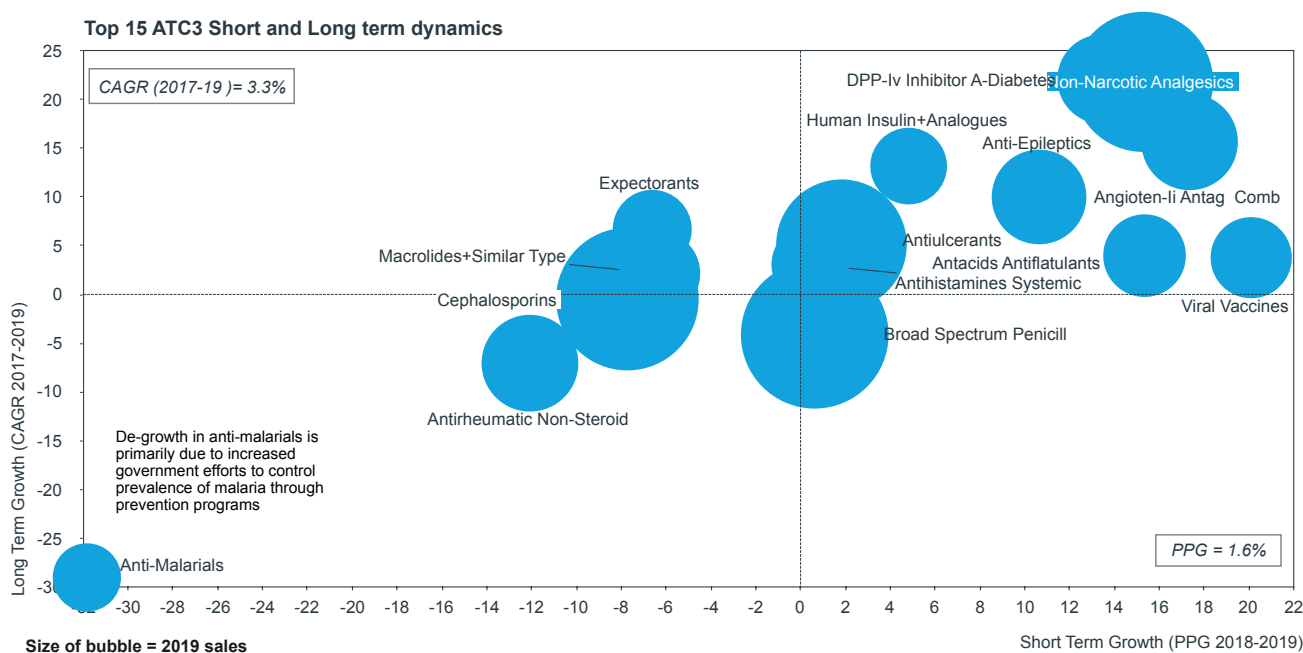


TABLE 10: TOP 15 MOLECULES, SALES AND SHARE OF LOCAL PLAYERS

Serial no.	Molecule types	Total private sector retail sales	Share of local players
1	Top 15 molecules total (by sales value in the private retail sector)	141	12%
2	Broad spectrum Penicillin	19	24%
3	Cephalosporins	18	10%
4	Nonnarcotic analgesics	17	20%
5	Anti-ulcerants	15	2%
6	Antirheumatic nonsteroids	8	12%
7	Angiotensin II receptor blockers	8	17%
8	Anti-epileptics	8	11%
9	Dpp-iv inhibitors for diabetes	7	4%
10	Macrolides and similar types	6	13%
11	Antacids and antiflatulants	6	6%
12	Antihistamines (systemic)	6	15%
13	Viral vaccines	6	0%
14	Expectorants	6	12%
15	Human insulin analogues	5	0%
16	Antimalarials	4	18%

sector retail market, followed by nonnarcotic analgesics. When the long-term and short-term growth rates of various ATC3s were compared, it was evident that sales of nonnarcotic analgesics have been growing at a higher rate than the other ATC3s.

A closer look at the top 15 molecules (by sales value) shows that multinational companies have 87 percent of the market share, dominating in most formulation categories, excluding the penicillin-type antibiotics Amoxicillin and Flucloxacillin, and the diabetes treatment Metformin, where local manufacturers also have a significant market share at 47 percent, 68 percent, and 45 percent respectively. Other molecules in which local players have significant market share are the analgesic Paracetamol and the antibiotic Ceftriaxone, with 23 percent and 13 percent market share, respectively.

In summary, the results of the data analysis mainly show that the multinational companies dominate the pharmaceutical market in Kenya by value, and the local manufacturers dominate by volume. The local manufacturers have focused on production and supply of off-patent generic products. Most of the multinational companies import products from their production facilities elsewhere (in Africa or other parts of the world).

3.8.2 Profiles of respondent pharmaceutical manufacturers

Six pharmaceutical organizations were purposefully sampled in Kenya and subjected to the survey in line with the Terms of Reference. These organizations and the results of the survey and data analysis are discussed below.

Manufacturer 1: Leading pharmaceutical manufacturer

Manufacturer 1 has the second-highest sales value in Kenya. It is fully Kenyan owned, is located in Nairobi, and employs over 500 people.

Markets and products: The company has a market presence in nine Sub-Saharan African countries, including in the EAC, Ethiopia, Botswana, DRC, Malawi, and Somalia. It is GMP compliant and SRA approved, and the compliance procedure for WHO prequalification is ongoing. It produces more than 300 formulations containing 180 APIs and has both branded products and generics. Its key therapeutic areas of focus are diabetes, cardiovascular, essential medicines, antiretrovirals, and veterinary medicines.

Revenue and cost structure: Its annual revenue is \$19 million, with a projected annual growth rate of 15 percent. A significant part of its expense, 50 percent, relates to the procurement of raw materials, followed by workforce remuneration at 25 percent.

Utilities: Its primary source of electricity is the national grid (Kenya Power and Lighting), which accounts for about 90 percent of its power needs. Its annual cost of electricity consumed is \$360,000. Water supply costs \$60,000 annually, with all needs met by borehole water.

Workforce: Many of the employees (230) work in the production department. There are 300 untrained laborers, which is a significant proportion of the workforce. The company employs 40 chemists, 10 engineers, 48 managers/supervisors, two pharmacists, and four pharmaceutical technologists.

Manufacturer 2: Leading manufacturer in the region

Manufacturer 2 is ranked among the top three domestic manufacturers in Kenya. It is fully Kenyan owned, is based in Nairobi, and employs over 500 people.

Markets and products: Its key markets are in EAC and southern African countries. It is also certified to engage in tenders for USAID/CHAI/International Dispensary Association/Mission Pharma. The company produces over 250 formulations in the branded, over-the-counter, and generic product categories.

Revenue and cost structure: The company's annual revenue is \$21 million and it is growing at a significant rate. Key components of its expenses are raw materials (38 percent), packaging (25 percent), and taxes and tariffs (20 percent).

Utilities: The cost of electricity is high, with its bills averaging \$500,000 per year.

Production capacity: The company has spare capacity, with current utilization standing at 60 percent. If needed, it could increase production dramatically by running three work shifts instead of one, as it currently does. At full capacity, it can produce 9 million tablets, 5 million capsules, 6,000 liters of oral liquid formulations, and 500 kg of ointments and creams for topical application daily.

Workforce: The company has 400 employees in the production department. It employs 29 chemists, 30 engineers, 78 managers/supervisors, four pharmacists, and 18 pharmaceutical technologists.

Manufacturer 3: Leading manufacturer with export-oriented business

Manufacturer 3 is one of WHO's pre-qualified pharmaceutical companies in Kenya. It is partially owned by a foreign entity (Strides Shasun, an Indian pharmaceutical company) and three local shareholders.

Markets and products: Its primary source of revenue is exports to 19 countries, mostly in Sub-Saharan Africa, as well as Afghanistan and Pakistan. Exports account for 75

percent of total revenue. The company is planning to move into markets for antiretroviral, antimalarial, diabetic, and cardiovascular drugs.

Revenue and cost structure: Its annual revenue is \$25 million. Procurement of raw materials constitutes a large part of its costs, at \$14 million per year. The company is fully dependent on imported raw materials. It uses 30 percent of its capacity to produce its tablet line.

Utilities: Water is supplied by its borehole. All electricity is provided by Kenya Power and Lighting, costing between \$480,000 and \$600,000 per year.

Manufacturer 4: Small local pharmaceutical manufacturer

Manufacturer 4 is a small manufacturing company based in Nairobi, with about \$2.7 million in annual revenue. It has 100 employees. It is fully Kenyan owned. The company has basic licenses from the PPB only.

Markets and products: Its key market is domestic (mainly Nairobi) and neighboring countries. Products include analgesics, antihelminthics, anti-infectives, cough syrup, and nutritional and veterinary items. The company produces 33 medicinal and 12 veterinary products.

Cost structure: The company's key costs are for raw materials (40 percent), packaging (20 percent), and workforce remuneration (33 percent). It sources most of the raw materials for packaging locally, while importing all APIs and excipients.

Utilities: It does not have a borehole and gets its water supply from the public utility provider. All its electricity supply is from the national grid, for which it pays about \$24,000 annually.

Production capacity: The company has spare production capacity, with current use varying between 20 percent and 70 percent depending on what is being produced.

Workforce: Untrained labor comprises 50 percent of its staff. Most of its employees (21) work in the production department. The company employs five chemists, three engineers, 16 managers/supervisors, one pharmacist, and one pharmaceutical technologist.

Manufacturer 5: Multinational company

Manufacturer 5, a fully owned subsidiary of a foreign multinational, is setting up a manufacturing plant in an EPZ in Kenya.

Markets and products: The company will primarily focus on manufacture and supply of IV fluids. It is globally GMP compliant, and its key markets will be Zambia, Ethiopia, and the EAC countries. The therapeutic areas have been

identified and the product range determined. The 30 products to be produced are in the ophthalmic, antibiotics, and injectables categories. Most of the needed APIs and excipients are imports.

Manufacturer 6: Generic manufacturer with foreign investment

The company is one of the major pharmaceutical companies in Asia. It is setting up manufacturing in Kenya in an EPZ. Currently, it has over 100 employees in the import business.

Markets and products: Its planned target market is East Africa, COMESA, West Africa, and South Africa. It is preparing for PPB accreditation. It plans to produce 42 generic products in the therapeutic areas of antacids, digestive stimulants, antidiarrheal medicine, antibiotics, antidiabetics, antipsychotics, and analgesics.

Revenue: Its current import revenue is \$4 million. In summary, the results of the survey of the six pharmaceutical manufacturing companies in Kenya clearly indicate variations in:

- Capacities and sizes of current operations
- Spatial locations and access to complementary services
- Breadth of target markets and product ranges
- Ownership arrangements
- Utilized capacity
- Sources and costs of water and electricity used
- Revenue streams and annual revenue generated.

Despite each company being unique, certain attributes are shared with peers in Kenya.

3.8.3 Comparing Kenyan pharmaceutical organizations with foreign peers

The opening of borders to trade in goods and services and the free movement of labor and capital with globalization has made it both easy and difficult for countries and companies to do business. Globalization has improved access to information, goods and services, low-cost and skilled labor, and sources of capital to finance investments. It has also increased competition for countries as sources and markets for information, goods and services, low-cost and skilled labor, and capital.

The countries that were once competitive locations for the manufacture of goods and services are facing competition at home and abroad. Companies that were once shielded in their countries and markets are facing competitive threats from global markets. To be competitive as an investment destination for investors, countries are reviewing their policies, creating enabling environments, instituting incentive schemes, and constantly benchmarking against peers to learn and undertake appropriate changes to become or remain a preferred destination for investments.

For Kenya to achieve its aim of becoming a regional hub for the manufacture and supply of quality pharmaceutical products and services, it must be able to attract investments and improve the performance of the local pharmaceutical sector.

A comparative survey was conducted to identify and map the important factors or conditions that confer an advantage to:

1. A country as a pharmaceutical business location
2. Pharmaceutical manufacturing companies in one country compared to those in another in the fight for market share locally and globally.

3.8.3.1 Comparative analysis of peer countries as a pharmaceutical business location

Four peer countries were chosen for comparison with Kenya: Egypt, Ethiopia, South Africa, and Bangladesh. (See Table 11.)

3.8.3.2 Benchmarking of Kenyan pharmaceutical manufacturers with peer companies

Nine pharmaceutical manufacturing companies from Kenya and the four peer countries identified were chosen for comparative analysis, as follows:

- Four private pharmaceutical companies in Kenya (three are locally owned and the fourth has foreign shareholding).
- One publicly listed company in Egypt.
- One publicly listed company in Bangladesh.
- Two companies owned by the same parent company in South Africa.
- One private company in Ethiopia.

These companies were assessed across multiple parameters. The highlights of the comparison are as follows:

- Kenyan manufacturers sell less of their products locally and export more than companies in other countries.
- Utility (water and electricity) costs are higher in Kenya.
- The average revenue per local manufacturing company in Kenya is low compared to that in other countries. This is largely a consequence of the high cost of utilities and transport of goods and the country's dependence on imported inputs, including the APIs and quality packaging materials. The Kenyan pharmaceutical market is dominated, in value, by foreign multinationals.
- The cost of packaging materials in Kenya appears to be higher than that in peer countries.
- Workforce costs in Kenya are lower than in regional peer markets.

The results of the survey and key attributes considered are shown in Table 12.

TABLE 1 1: RESULTS OF COMPARATIVE ANALYSIS OF PEER COUNTRIES ON PHARMACEUTICAL MANUFACTURING

Parameter	Comparative advantages	Disadvantages
Kenya	Strategically located to be able to serve the local (East African market) and regional market covering the entire of Africa Low costs of labor	Heavily dependent on imports for packaging material with high costs High utility costs with poor quality of electricity Low utilization of installed manufacturing capacity Slow and inefficient regulatory processes
Egypt	Low costs associated with packaging material Low costs associated with taxes	High costs associated with the marketing of products Poor performance in ease of doing business Lack of incentives for local manufacturing
Ethiopia	Low costs associated with utilities Low wage rates Incentives for local manufacturing (30% price preference, 30% pre-payment, tax exemption on exports, tax-free periods)	Low productivity of labor Access to foreign exchange is a challenge Quality of electricity is poor
South Africa	High productivity of labor Many investment summits are held to attract investments Presence of ancillary industry of spare parts	High costs associated with utilities High wage rates Prices are regulated by the government
Bangladesh	Low costs associated with raw material and workforce salary Incentives from the government for exporting products (10% of freight-on-board value, i.e. value of goods excluding carriage, insurance, and freight, which is almost equal to the domestic price in the country of origin) Easy access to raw materials	High costs associated with taxes and distribution Pharma manufacturers have to invest in inhouse power generation capacities

Globalization has improved access to information, goods and services, low-cost and skilled labor, and sources of capital to finance investments. It has also increased competition for countries as sources and markets for information, goods and services, low-cost and skilled labor, and capital.

TABLE 12: BENCHMARKING OF KENYAN PHARMACEUTICAL COMPANIES AGAINST LOCAL AND REGIONAL PEERS

Parameter	Kenya	Egypt	Ethiopia	South Africa	Bangladesh
Market size (US\$ million)	700–800	6,000	550	3,580	2,800
Local selling vs export	78% vs 22%	90% vs 10%	100% vs 0%	99% vs 1%	95% vs 5%
Locally manufactured vs imported in companies interviewed	99% vs 1%	70% vs 30%	100% vs 0%	62% vs 38%	
Average revenue (\$ million)	14	32	24	129	550
Expense (\$ million)	12	28	13		435
- Raw material	42.0%	57.1%	42.8%	65.3%	28.7%
- Packaging	19.6%	2.9%	14.2%	7.3%	13.5%
- Workforce salary	19.3%	27.4%	27.4%	7.0%	5.7%
- Distribution costs	0.7%	-	2.1%	2.0%	17.8%
- Tax and tariff	13.8%	4.1%	13.0%	-	27.0%
- Utility	2.6%	1.1%	0.1%	2.5%	1.4%
- Marketing	3.2%	6.3%	0.5%	2.0%	2.7%
- Research and development	0.8%	1.7%	0.04%	-	-
Margin	15%	12%	43%		21%
Electricity consumption – supplied vs generated	97% vs 3%	100% vs 0%	100% vs 0%	90% vs 10%	
Electricity cost per revenue of \$1 million	250,000	60,000	5,000	88,000	
Capacity utilization	30–60%			70–90%	90%
Wage rate (\$ per month at entry level)	2,000	1,750	470	8,330	
- Managerial	700	220	250	1,670	
- Site supervisor	2,500	320	200	2,500	
- Engineer	1,500	510	180	-	
- Microbiologist	350	510	180	1,670	
- Chemist	2,000	190	300	3,330	
- Pharmacist	200	170	150	2,500	
- Other skilled	200	75	45	830	
- Unskilled					

TABLE 13: COMPARISON OF COUNTRIES ON VARIOUS FACTORS RELEVANT FOR PHARMACEUTICAL SECTOR

Parameter	Kenya	Egypt	Ethiopia	South Africa	Bangladesh
Location	<ul style="list-style-type: none"> Location close to Nairobi to access skilled labor and expatriates 	<ul style="list-style-type: none"> Location closer to Cairo for better access to universities, manpower, government 	<ul style="list-style-type: none"> Location closer to port 	<ul style="list-style-type: none"> Location with accessibility to ports and good connectivity 	<ul style="list-style-type: none"> Location closer to river-based transport
GMP implementation	<ul style="list-style-type: none"> GMP implementation is poor with lack of expertise in this domain among personnel 	<ul style="list-style-type: none"> Implementation of GMP is not done properly. GMP requirements are not treated seriously by personnel 		<ul style="list-style-type: none"> Local regulatory authority (SAHPRA) is building capacity and moving towards SRA (stringent regulatory authority) status 	<ul style="list-style-type: none"> With expert focus, companies usually have some global accreditations including WHO GMP and PICS
Ease of doing business	<ul style="list-style-type: none"> Improving ease of doing business through One Stop Shop and facilitating hassle-free setting up of business 	<ul style="list-style-type: none"> Poor, no new plants are opening. Only existing plants are being purchased by investors 	<ul style="list-style-type: none"> Accessing forex for purchasing API and other requirements is a challenge 	<ul style="list-style-type: none"> Mature market with well established systems, lot of investment summits are happening Labour unrest is a barrier to business 	<ul style="list-style-type: none"> No duty on APIs Higher duty for packaging material if imported
Regulatory processes	<ul style="list-style-type: none"> Regulatory processes are slow and take longer than the established timelines for approvals Inefficiencies exist in the system 	<ul style="list-style-type: none"> Starting a business is easy but operating is a problem Regulatory processes allows limited products for a molecule to be registered leading to intense competition 	<ul style="list-style-type: none"> Highly supportive of local manufacturers Manufacturing license, registration of products, marketing authorization are instantaneous for local companies 	<ul style="list-style-type: none"> Backlog for product approvals has decreased, now taking up to one year instead of up to four years Prices are regulated by government. However, launch price may be set by manufacturer 	<ul style="list-style-type: none"> Manufacturing license does not require too much time if all paperwork is in order For generic products, approval is faster compared to new products which requires a lot of information
Incentives for local pharma manufacturers	<ul style="list-style-type: none"> Price preference of 15% in public procurements for local manufacturers Faster approval for local manufacturers 	<ul style="list-style-type: none"> No incentives for local manufacturers 	<ul style="list-style-type: none"> 30% advance payment for public tenders 30% price preference in public tenders tax exemptions for exports 		<ul style="list-style-type: none"> Government pays 10% of freight-on-board value for exports
Availability of inputs	<ul style="list-style-type: none"> Raw materials have to be imported Access to skilled manpower is a challenge Electricity is costly and of poor quality 	<ul style="list-style-type: none"> No challenges with utilities Access to manpower is good Equipment has to be accessed from abroad but this is not a challenge 	<ul style="list-style-type: none"> All inputs are imported and lack of access to forex is a challenge Electricity was unreliable but is improving 	<ul style="list-style-type: none"> Key equipment is sourced from India/Korea while consumables and smaller spare parts are available locally Electricity has improved substantially Access to quality water is good 	<ul style="list-style-type: none"> Raw materials are easily accessible through ports in India and China Good access to manpower Pharma companies have in house electricity generation plants due to previous disruptions

3.9 Investors and investment trends

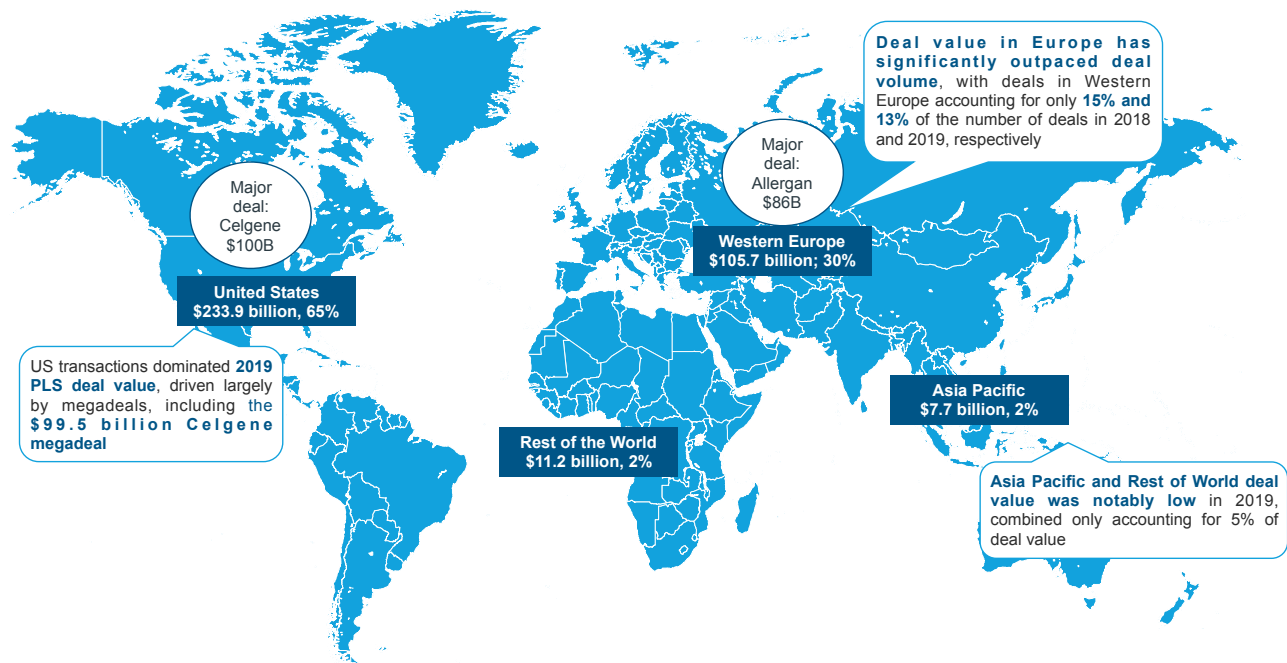
3.9.1 Global investments and investors

The global market for pharmaceuticals and life sciences is expected to grow at an annual rate of 3 percent to 6 percent to reach \$1.5 trillion by 2023. To increase their scale and their competitiveness for resources and market share, pharmaceutical companies are looking to acquire new technology and intellectual property, and to develop new drugs. Most mergers and acquisitions are driven by the need to boost scale, increase research and development, widen the product range, and expand market reach. The biotechnology companies' subsector experienced the largest increase in value of deals made globally in 2019 compared to 2018, with six megadeals made. This trend is expected to continue. The medical devices sector experienced a decline in both the number and value of deals completed in 2019 compared to prior years.

Most of the deals in the pharmaceutical life sciences industry were in the U.S. market, totaling \$233.9 billion (65 percent of global deal value), followed by Western Europe at \$105.7 billion (30 percent of global deal value). In Asia Pacific and the rest of the world, the value of deals made was notably low in 2019 and accounted for just 5 percent of total deal value.¹⁰²

The outlook for investment deals in the pharmaceutical and life sciences sector is positive. To compete more effectively with larger producers of generics in the market, medium-sized players need to add scale through mergers and acquisitions. The cell and gene therapy (oncology and rare disease) subsectors will likely continue to be key therapeutic areas of focus. For the over-the-counter sector, scale and innovation are important factors for success.

FIGURE 38: GLOBAL PHARMACEUTICAL DEAL SIZE BY LOCATION



The following are key private equity investors in the global pharmaceutical and life sciences industry:



FIGURE 39: KEY PHARMACEUTICAL INVESTMENT DEALS IN AFRICA (NON-EXHAUSTIVE)



3.9.2 Regional investments and timeline

It is evident that generic medicines are gaining popularity in African pharmaceutical markets. In South Africa, Egypt, Algeria, Morocco, Nigeria, and Kenya, the generics sector grew at an average compound annual growth rate of 22.3 percent between 2004 and 2011, which is much faster than the 13.4 percent for the overall pharmaceuticals market. In Africa, prescription drugs are predicted to grow at a compound annual rate of 6 percent, generics at 9 percent, over-the-counter medicines at 6 percent, and medical devices at 11 percent.

The key drivers for growth in the generics segment on the continent are physicians' and pharmacists' greater acceptance of generic drugs, leading to more prescriptions for these; the national medical insurance program's intention to reduce treatment costs; rising health-seeking behavior in the population; and greater access to health care. Many African governments are showing strong support for the use of generic medicines.

The huge variance in regulatory requirements and health needs across countries on the continent is a key concern for investors in the space. In-depth knowledge of intra-African and regional market differences is vital. Approximately 85 percent of the African pharmaceutical market value is located in the top 15 countries. The greatest growth and potential are in Nigeria, Kenya, and Ethiopia, where this annual rate has been in the double digits.

3.9.2.1 Private equity activity in Africa

In Africa, many companies are still run by their founders or founders' families. Most of these individuals are afraid to relinquish control of their companies or open up to new investors. Some of these businesses still rely on informal practices, such as providing "gifts" (bribes) to obtain an import license. There is often limited depth to the management skills and capabilities in companies on the African continent, especially in the ranks below top management. Many African governments have limited the extent of foreign ownership in order to encourage local economic empowerment. For example, South Africa has a new Investments Bill that seeks to ensure 51 percent local ownership of companies in the country. This Act is a Private Industry Regulatory Act Amendment Bill, commonly known as the Security Bill.

In general, while investors can put their money into the pharmaceutical or any other industry in Africa, the unwillingness of company founders (and their families) to relinquish control to investors and the increasing desire and attempts by governments to increase citizen ownership of firms within their borders have discouraged foreign investment. But, given the great variations in each country's legal, regulatory, and other market characteristics, there is a need to map opportunities to help those wishing to enter the pharmaceutical sector in Africa.

FIGURE 40: CHALLENGES FACED BY PRIVATE EQUITY IN AFRICA

Working with owners and founders

In Africa, many companies are still run by their original founders or their families, with many afraid to relinquish control to new investors.



A limited talent pool

There is often limited depth to the management skills and capabilities in African companies; this is particularly true below the top management level.

Opaque business practices

In many African countries, some businesses are still reliant on informal practices such as providing “gifts” to obtain an import license.



Indigenization trends

Many African governments encourage local economic empowerment by limiting the extent of foreign ownership. South Africa’s proposed bill for 51% local ownership of private security companies is one example.

3.9.2.2 Investors’ perceptions of Kenya

Market sentiments and/or perceptions are important drivers of investment decisions and of countries’ and companies’ performances globally. An overtly positive image of a country and its companies can attract investment, while a negative one can discourage it. Access to more information about market potential, positive environmental factors, and government efforts to encourage investment can sway an investor’s choice of location and the type of business to invest in.

All survey respondents had a positive perception of and outlook for the Kenyan market. About 67 percent expect the local pharmaceutical market to have steady growth, and about 33 percent expect rapid growth. The key factors that affect investors’ decisions in any country (in order of importance) are:

1. Macroeconomic situation, customs, and trade regulations
2. Political situation, business licensing and permits, corruption, structure of industry, workforce quality, and tax rates
3. Law and order
4. Functioning of courts, infrastructure, level of competition, and labor regulations
5. Access to capital.

3.9.3 Kenya is an attractive investment location

To achieve Kenya’s goal – outlined in its Vision 2030 – of becoming a regional hub for the manufacture and supply of quality pharmaceutical products and services, the government must attract investment by creating an enabling environment, instituting incentive schemes, benchmarking against peers, and adjusting policies where appropriate.

FIGURE 41: KEY FACTORS FOR INVESTMENT DECISIONS

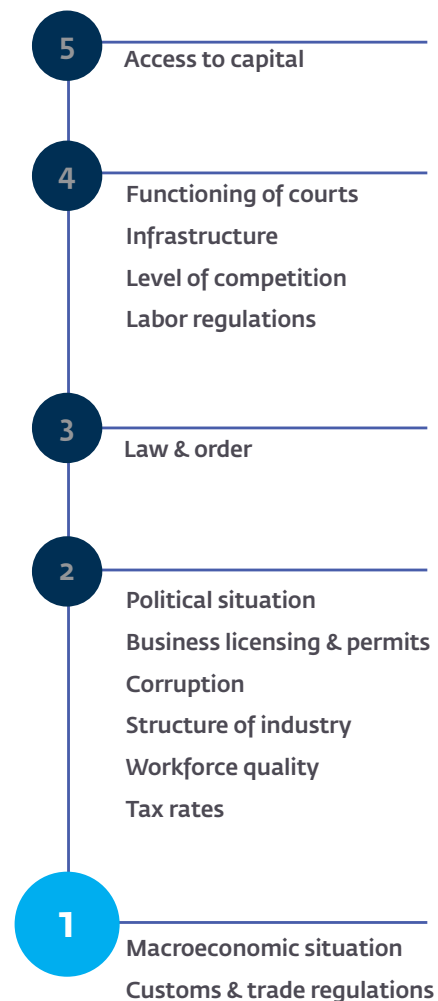


TABLE 14: IMPORTANT FEATURES OF THE KENYAN PHARMACEUTICAL MARKET (ACCORDING TO SURVEY RESPONDENTS)

Positive: Encourages investment	Negative: Discourages investment
Government policy that boosts investments in the sector	Poor market regulation with counterfeit drugs being common in the market
Strategic geolocation for importing raw materials from India and China	Many companies are not GMP compliant
Cross-border trade and access to export markets in EAC and COMESA	Low per capita income; low buying power of the majority of citizens
Many large investment banks have branches in Kenya; private equity funds have made investments in health care	Perceived high index of corruption
A thriving local manufacturing sector in the region	Unreliable supply of utilities (water and electricity)
English is commonly used for communication and trade in the country	
Ease of starting a business	

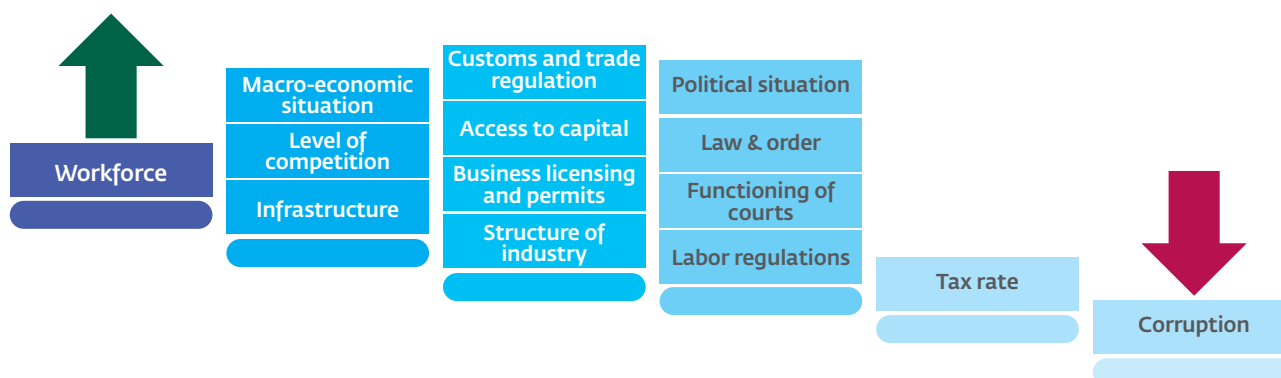
Survey respondents indicated their considerations for choosing Kenya as an investment location. At the top of the list are the market prospects of the Kenyan and East African region. Next are incentives provided by the government, including duty exemptions/tax relief and support for processing necessary documents to meet regulatory requirements, and subsidies for the construction of infrastructure. Other considerations include a skilled labor force, low labor costs, and low land prices.

Manufacturing attracts the most investment in Kenya, as the subsector brings high return on investment. It benefits from the government’s policy of reducing Kenya’s dependency on imports, which creates opportunities for import substitutions. Distribution is the segment next most preferred by investors, primarily because almost 60 percent of pharmaceutical products are imported and so those engaged in distribution earn a good return on investment.

Survey respondents provided a mixed characterization of the challenges relating to human resources in the country. During qualitative discussions, they mentioned limited skills in the workforce in Kenya as a deterrent, yet in the quantitative survey, they rated the country highly on the workforce parameter. The lack of required skill sets, such as specialized production and development of new formulations, is seen as a deterrent, whereas the abundance of labor in general (as Kenya has a very youthful population joining the labor pool each year) was viewed as a positive factor.

Respondents rated Kenya low on corruption and tax rates, while perceiving the country to have favorable conditions with respect to the workforce. They also rated Kenya high on its macroeconomic situation and level of competition.

FIGURE 42: SCORE OF KENYA ON DECISION FACTORS



3.9.4 How Kenya's investment attractiveness compares with peers

Key features were identified to compare Kenya against peer countries with interests in pharmaceutical manufacturing, as shown in Table 15. The aim was to learn from the comparison so that Kenya can make appropriate changes to become a preferred destination for investment in the pharmaceutical sector.

Respondents cited corruption as a major deterrent, as well as high tax rates. In comparison with other investment destination countries like Cameroon and Tanzania, Kenya scored poorly on the corruption perception index. Workforce quality was rated highly. High competition from local manufacturers, as well as imports into the country, are other major challenges that investors consider, as shown on the next page.

3.9.5 Fitting profiles of potential entrants

Analysis of country and industry data can be used to develop an indicative description of a model organization that sets up, operates, and thrives if it crafts and effectively implements a full business plan. Following the diagnostic survey, modeling was done of the requirements for a potential investor wishing to enter Kenya's pharmaceutical

manufacturing and distribution sectors. The suggested profiles are as follows.

3.9.5.1 The manufacturing sector profile

This is a conceptual profile of an investor (Y) wishing to enter the manufacturing sector to produce and supply generic, essential, and opportunistic medicines. The ideal size of their workspace is between 100,000 square meters and 200,000 square meters. The annual projected revenue is \$22 million. The projected workforce needed to support the organization effectively would be as shown in Table 16.

3.9.5.2 The distribution sector profile

This is a conceptual profile of an investor (Z) wishing to enter the pharmaceutical distribution sector. The company will focus on the distribution and retail of all types of pharmaceutical products. There will be 60 locations to ensure optimal coverage and to respond effectively when filling orders received. The total number of employees by specialization would be 200, spread over various departments: Quality Assurance (two), Regulatory (two), Sales and Marketing (five), and Others (about 200).

The expenditure attributes for both the manufacturing and distribution sectors in Kenya are presented in Table 17.

TABLE 15: RATING OF KENYA VS OTHER INVESTMENT DESTINATIONS ON KEY DECISION FACTORS

	South Africa	Côte d'Ivoire	Cameroon	Tanzania	Kenya
Reason	Attractive PE opportunities	Leading in West Africa	High macro-economic prospects	Favorable government policies	Macro-economic situation
Political situation	●	●	●	●	●
Macroeconomic situation	●	●	●	●	●
Law and order	●	●	●	●	●
Functioning of courts	●	●	●	●	●
Business licensing and permits	●	●	●	●	●
Customs and trade regulations	●	●	●	●	●
Corruption	●	●	●	●	●
Level of competition	●	●	●	●	●
Structure of specific industry to invest in	●	●	●	●	●
Access to capital	●	●	●	●	●
Workforce quality (education, skills, language)	●	●	●	●	●
Tax rates	●	●	●	●	●
Infrastructure (transport, electricity, water, telecommunications)	●	●	●	●	●
Labor regulations	●	●	●	●	●

● Poor ● Neutral ● Good ● Very good

FACTORS DETERRING INVESTORS

From highly important to less important:

1. Limited pool of skilled pharma sector workforce
2. Unsupportive customs and trade regulations
3. Access to capital; business licensing and permits; structure of industry
4. Weak political situation; law & order; functioning of courts; labor regulations
5. High tax rates
6. Corruption

FACTORS ATTRACTING INVESTORS

From highly important to less important:

1. Market prospects of Kenya and East African Region
2. Duty exemptions for material and equipment
3. Already present in Kenya; access to low cost labor
4. Benefits from local government
5. Low price of land/easy availability of land
6. Attractive trade agreements
7. Subsidies from local government
8. Macroeconomic indicators, competition, infrastructure

TABLE 16: EMPLOYEES FOR COMPANY Y

Employees	Number	Employees	Number
By specialization		By department	
Trained pharmacist	15	Research and Development	9
Analytical chemist	45	Production	200
Microbiologist	3	Quality Assurance	70
Other	100	Regulatory	5
		Sales and Marketing	25
		Others	200

TABLE 17: EXPENDITURE (AS % OF REVENUE) FOR TARGET PROFILE FIRMS

Manufacturing sector	Distribution sector
<ul style="list-style-type: none"> ■ Utilities: 4% ■ Raw material costs: 65% ■ Sales and Marketing: 5% ■ HR and Payroll: 16% ■ Legal costs: 0.3% 	<ul style="list-style-type: none"> ■ Rent: 15% ■ Utilities: 5% ■ Sales and Marketing: 5% ■ HR and Payroll: 20% ■ Legal costs: 5%

3.10 Opportunities

3.10.1 Domestic market opportunities

According to the EAC report, Kenyan manufacturers currently hold 30 percent of the \$1 billion Kenyan pharmaceutical market. Hence, there is an opportunity for investors to cater to the remaining 70 percent.

3.10.2 Export market opportunities

Export markets could drive the growth of the local pharmaceutical industry in Kenya. The EAC and COMESA regions are key destinations for the products of Kenyan manufacturers. According to a report from a United Nations Conference on Trade and Development,¹⁰³ the East African pharmaceutical market is worth about \$5 billion, and only 30 percent is met by local manufacturers.

This presents an opportunity for local manufacturers in Kenya to produce health products at scale and of the required quality to meet the demand of EAC countries.

The target market for local exports of pharmaceutical products is COMESA, EAC, and the rest of Africa, where the total market is valued at \$13.6 billion. Kenya is only able to export an average of \$63 million worth of products to these regional markets. A 5 percent increase in Kenya's share of this total African market will translate to exports worth \$678 million.¹⁰⁴

3.10.3 Therapeutic area opportunity

According to the EAC regional pharmaceutical manufacturing action plan, domestic pharmaceutical manufacturers have a strong presence in anti-infective product categories such as cough and cold preparations, antiprotozoals, antiseptics, antiasthmatics, and antibiotics. However, there is also a huge demand for immunological and cardiovascular therapies that is not covered by domestic manufacturers. This presents a good opportunity for investors to set up manufacturing plants for immunological and cardiovascular drugs.

FIGURE 43: DOMESTIC PHARMACEUTICAL OPPORTUNITY FOR INVESTORS

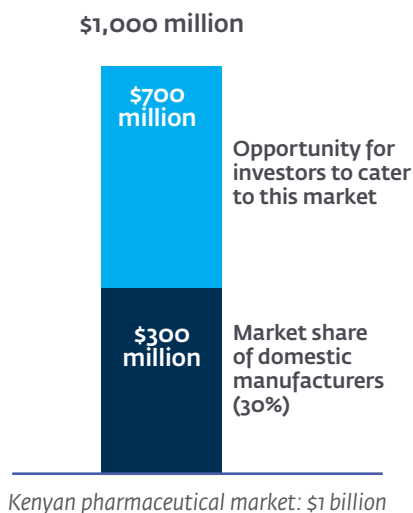
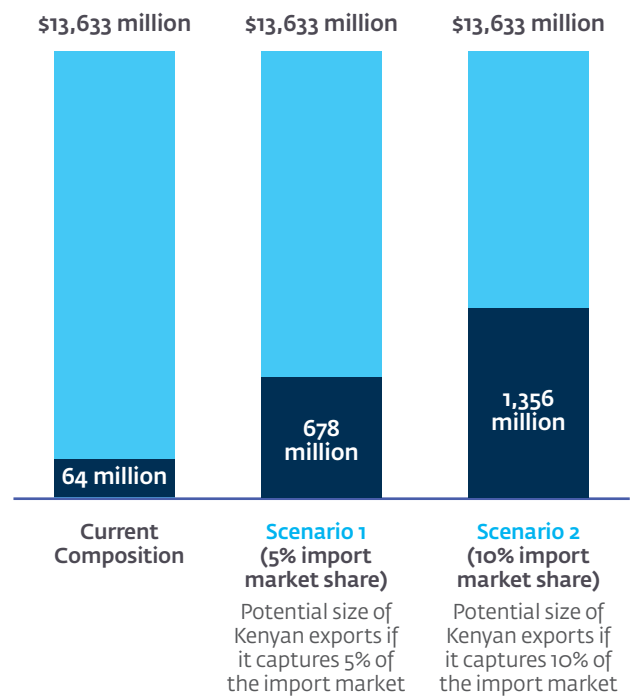


FIGURE 44: EXPORT OPPORTUNITY SIZE AND SCENARIOS FOR INVESTORS





According to the EAC report, Kenyan manufacturers currently hold 30 percent of the \$1 billion Kenyan pharmaceutical market. Hence, there is an opportunity for investors to cater to the remaining 70 percent.

04



Recommendations

Based on analysis of Kenya's pharmaceutical sector, the following recommendations are presented for policy consideration.

Develop a national 10-year strategic plan for the development of the pharmaceutical sector

Based on the work done in the EAC Regional Pharmaceutical Plan of Action 2017–2027, Kenya needs to develop and implement a national 10-year strategic plan to transform the pharmaceutical sector by 2030 into a competitive regional hub for manufacturing pharmaceutical products, including drug formulations for noncommunicable diseases, APIs, excipients, and veterinary medicines.

Political ownership and support

Political leadership and support is needed to ensure that local pharmaceutical manufacturing issues remain on the agenda at the highest level in government. This will help inspire stakeholders to take necessary actions. It is necessary to:

- Strengthen the pharmaceutical sector agenda and representation in the National Investment Council, particularly in order to prompt government engagement with the private sector in pharmaceutical manufacturing and associated clusters.
- Include the performance metrics of the pharmaceutical industry (manufacturing and the entire value chain) so that performance can be monitored and reported to the relevant House and Senate Committees under the Big 4 Agenda in the National Investment Council.

Legal landscape

There are many complementary laws aimed at spurring the local manufacturing industry (including pharma) and the distribution of its products in Kenya. However, these fall within the mandate of different government ministries. It is necessary:

- To create a multisectoral committee to own and facilitate the review and implementation of laws targeting Kenya's manufacturing industry (especially for health products).
- To set a clear timeline (perhaps every five years) for reviewing and reporting on the prevailing environment in Kenya (and regional markets). Laws in force to encourage

local manufacturing also need to be reviewed to ensure they remain appropriate and relevant.

- For the government of Kenya to monitor and advocate for laws and policies in the EAC and COMESA trading blocs that do not restrict its exports.
- To harmonize investment laws in Kenya and ensure that Kenya positions itself to benefit from the African Continental Free Trade Area and other priority regional economic communities.

Regulatory landscape

Multiple regulatory bodies govern function and practice in the pharmaceutical sector. Some fall within the sector and Ministry of Health, while others are with other government ministries. There is, therefore, a need to:

- Develop an Inclusive Coordination Framework that ensures a more harmonized approach in the regulation of the pharmaceutical industry and adequate involvement and representation of the sector.
- Implement the existing regulatory policies, and measure and report on performance to the relevant Senate and House related subcommittees via the National Investment Council, including on the regulation of the manufacturing and retail pharmacies subsectors.
- Clarify the roles and responsibilities of the NQCL and the PPB. Although the law clearly states their respective responsibilities, there is a perceived conflict between the two entities. Their responsibilities must be clarified to increase their collaboration and ensure they can fulfill their mandates.
- Undertake a workload assessment to ensure sufficient resources are provided to the PPB and the NQCL so that they can perform their roles effectively.
- Conduct a nation-wide assessment of pharmacy outlets to identify unregistered pharmacies and take corrective actions.
- Design policies to incentivize and support manufacturers achieving WHO prequalification or similar quality assurance compliance.

- Advocate for accelerated adoption of cross-recognition of common pharmaceutical regulatory standards and practices in the EAC and COMESA regions to create an enabling environment for Kenya's exports.

Human resources

There are skills gaps in Kenya's workforce. From the project research, it was observed that the industry finds that pharmacy courses are too theoretical and do not impart the practical knowledge required in manufacturing.

There is also a lack of specialized engineering skills to provide ancillary support services to pharmaceutical manufacturing. In order to tap the full potential of Kenya's human capital for pharmaceutical manufacturing:

- Policymakers and education specialists need to adjust the current education curricula to ensure that skills in the workforce are adapted to industry needs. Curricula should be based on competencies required and focus on acquisition of skills.
- Metrics need to be developed to measure outputs and outcomes of internships and on-the-job training. This will help incentivize the private sector to invest in training and mentorship programs for secondary and tertiary levels of education to nurture talent that can drive innovation.

Operational landscape

Certain operational challenges affect domestic pharmaceutical manufacturing, such as reliable electricity and water supply, bureaucratic processes, access to funds, and reliance on imported raw materials. For Kenya to become a hub for pharmaceutical manufacturing and a major exporter of pharmaceutical products to the rest of Africa, the following actions need to be taken:

- Local pharmaceutical manufacturers need to increase the efficiency and effectiveness of their operating models, re-engineer their operations, and take advantage of the current structural, tax, and financial reforms implemented by the government of Kenya. Adoption of technology and turnkey enterprise resource planning should be a required business standard for local pharmaceutical manufacturing firms as this will go a long way toward improving operational efficiency, reducing waste, and ensuring that products meet the highest quality standards.
- The government of Kenya should continue to ensure that the macroeconomic environment is conducive for business. It can do so by implementing responsive policies and improving standards of service within government institutions. Blockchain and artificial intelligence-based solutions for the industry could also

be explored to increase transparency and accountability internally for strategic business units and externally for role players in the value chain, including the supply chain.

- Provide the pharmaceutical manufacturing industry with the required infrastructure, such as a low-cost, reliable, and quality supply of electricity and water. This could be facilitated through common facilities in SEZs/EPZs.
- Ensure local low-cost quality inputs are available for manufacturing pharmaceutical products. Companies with credible capacity can be encouraged, through tax incentives and limited-period sovereign guarantees to credit, to access requisite technology for the production of APIs and excipients.
- Encourage pharmaceutical manufacturers to invest in strategic purchasing through integration into local trade networks that allow them to have negotiating power, both locally and internationally.

Research and development

Currently, the maturity level of pharmaceutical manufacturing is Level 1. The pharmaceutical industry will need to improve its maturity level and move to complex and high value-added production to reduce its reliance on imports. Research and development of new products in Kenya requires the combined effort of many stakeholders in the industry. It is especially important to ensure that:

- Both operational and scientific research are implemented by pharmaceutical manufacturers in partnership with academia, research institutions, and policymakers. This will provide much-needed evidence for strategic decisions on and investments in processes and products.
- Adequate research funds are made available from a national pool by both the public and private sector to reduce the limitations that hold back research work to find and develop new drugs and technologies in support of the local industry.

Improving access to local and regional markets

Brand Kenya is the agency mandated to promote Kenya's exports of goods and services and coordinate related activities. It needs to address policy issues with trade partners, address bottlenecks, create a platform for and actively promote Kenyan pharmaceutical products, and expand access to markets for Kenyan pharmaceutical manufacturers.

- To promote Kenyan products, the government of Kenya needs to use its embassies and trade missions to work with Brand Kenya.
- To increase domestic demand for locally manufactured pharmaceutical products, strategic partnerships need to be created with health-care providers – including hospitals, health-care franchises, and pharmacies – especially in the current environment, which is focused on the Sustainable Development Goals and universal health care. Pharmaceutical manufacturers should leverage the Buy Kenya Build Kenya strategy (and especially the preferential public procurement policy for locally produced pharmaceutical products) to increase local brand recognition and loyalty.
- To assure the quality of products and grow the market for exports, pharmaceutical manufacturers in Kenya should invest in GMP.

Improving Kenya's place as an investment destination

Globalization has increased competition among countries as sources for goods and services, low-cost and skilled labor, and capital. For Kenya to become more competitive as a destination for setting up pharmaceutical manufacturing industries:

- A comparative analysis needs to be done, every five years, of Kenya's current compelling offerings against those of its peers. The findings should be used to adapt local conditions and marketing as appropriate.
- A national 10-year pharmaceutical sector strategic plan and policy need to be developed. These will help Kenya create the conditions to become a competitive investment location for the manufacturing and export of pharmaceutical products.

The full implementation of these recommendations will enable Kenya to realize its goal of becoming, by 2030, a pharmaceutical manufacturing hub to meet local needs and export to the region. More specifically, the country will:

1. Reduce its current total dependence on imported APIs and excipients to 50 percent and grow its local capacity to produce more.
2. Increase the proportion of pharmaceutical manufacturers that meet national GMP standards from the current 65 percent to 100 percent, and support those manufacturers that comply with global GMP requirements.
3. Increase the proportion of national pharmaceutical products demand met by locally manufactured products

from the current 30 percent to about 65 percent.

4. Eliminate unregistered retail pharmacies in the country to minimize the risk of substandard products entering the supply chain.
5. Increase its market share from the \$63 million annually in pharmaceutical exports to the EAC, COMESA, and the rest of Africa to \$678 million (which translates to a 5 percent share of the \$13.6 billion market for pharmaceutical products in Africa).

Endnotes

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