



REPUBLIC OF KENYA  
Ministry of Health  
Ministry of Industrialization, Trade and Enterprise Development

# Kenya Pharmaceutical Industry

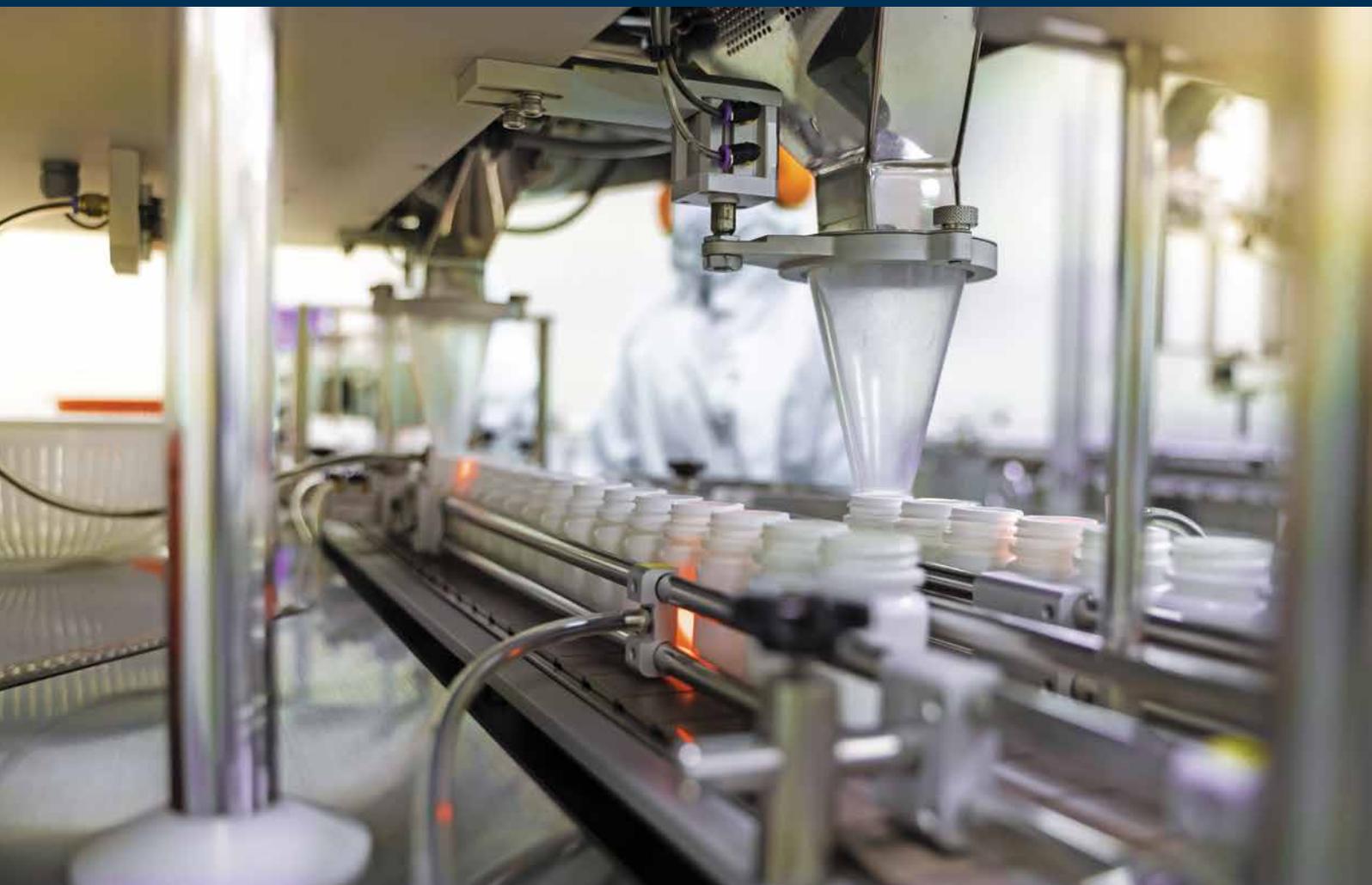
## DIAGNOSTIC REPORT 2020 – SUMMARY



PREPARED BY:



The Kenya Pharmaceutical Industry Diagnostic Report 2020 highlights and examines gaps, challenges, and opportunities in Kenya's pharmaceutical industry. The report recommends steps to spur the industry's growth and make it more competitive.



## BACKGROUND

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**K**enya aspires to be a healthy, productive, and globally competitive nation. The country's Vision 2030 and the Big 4 Agenda Programme launched in 2018 make clear the government's commitment to support citizens' health, create opportunities for education and employment, and transform Kenya into an industrialized country by 2030.

Developing the pharmaceutical manufacturing sector is a core part of building a progressive and sustainable health-care system that can respond to routine needs

and emergencies. The COVID-19 pandemic is one such emergency where access to quality health care is critical.

The Ministry of Health and the Ministry of Industrialization, Trade and Enterprise Development are the two key ministries collaborating to realize Kenya's goal of becoming a regional hub for the manufacture and distribution of pharmaceutical products. They are working with other stakeholders to ensure Kenya builds a more competitive local pharmaceutical manufacturing sector.

## DIAGNOSTIC SURVEY

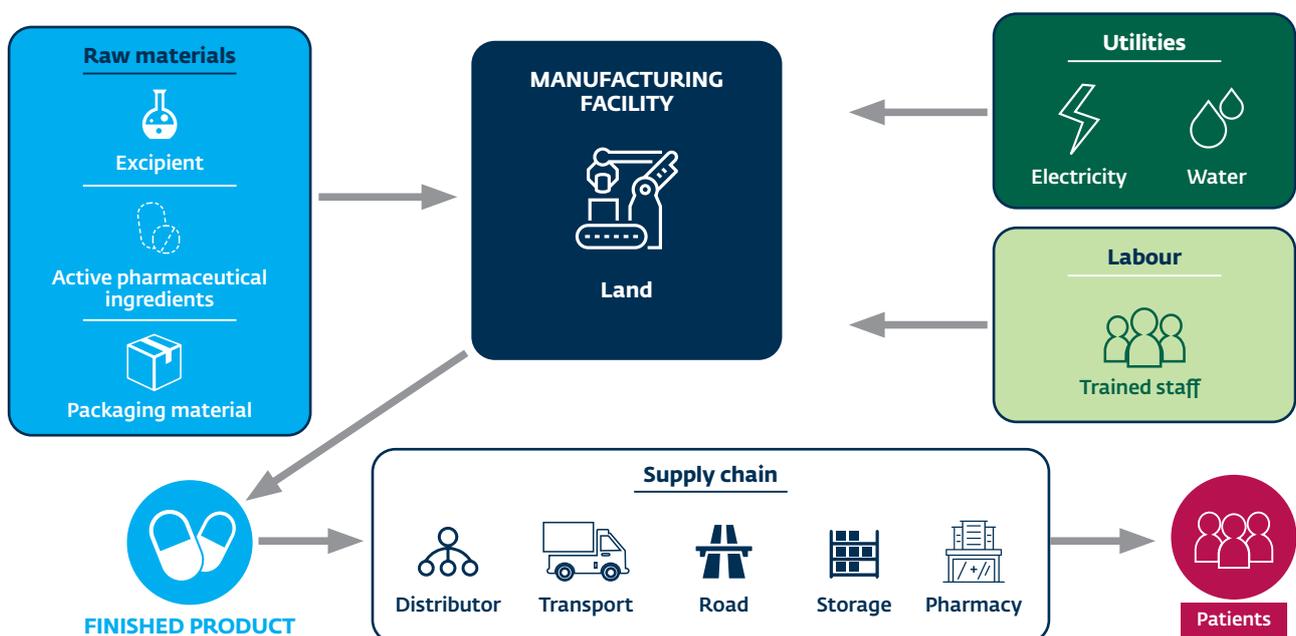
To inform policy interventions, a comparative survey was conducted of nine pharmaceutical manufacturing companies – four from Kenya and five from the peer countries of Bangladesh, Egypt, Ethiopia, and South Africa. The aim was to identify and map challenges and opportunities in the sector and highlight key attributes for attracting investment to Kenya’s pharmaceutical industry.

Extensive supporting data was collected through desk research, interviews with regulatory stakeholders and industry experts, surveys with investors, and a market-pricing survey of 30 pharmacies in three counties (Kisumu, Mombasa, and Nairobi). The data was analyzed to assess the current state of the industry and examine key challenges. Policy-level interventions were then proposed to enable the government of Kenya to address these challenges, promote the local pharmaceutical manufacturing industry, and attract a greater share of investment.

The report’s recommendations (outlined in more detail below) aim to enable Kenya to become a regional manufacturing hub of pharmaceutical products by 2030. The goal is for Kenya to:

1. Reduce its current total dependence on imported active pharmaceutical ingredients and excipients (inactive ingredients for stabilizing a drug, bulking it up, or enhancing its therapeutic effectiveness) to 50 percent and grow its local capacity to produce such products.
2. Increase the proportion of pharmaceutical manufacturers that meet national good manufacturing practices standards from 65 percent to 100 percent, and support local manufacturers that fully comply with global requirements for good manufacturing practices.
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 in pharmaceutical exports to the Common Market for Eastern and Southern Africa (COMESA), the East African Community (EAC), and the rest of Africa from \$63 million annually to \$678 million (which translates to a 5 percent share of the \$13.6 billion market for pharmaceutical products in Africa).

FIGURE 1: KEY REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURING



## FINDINGS

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 is higher in Kenya.
- Although workforce costs in Kenya are lower, local 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 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.

### Opportunities

#### Domestic market

According to the EAC Regional Pharmaceutical Plan of Action 2017–2027, Kenyan manufacturers currently hold 30 percent of the \$1 billion Kenyan pharmaceutical market. There is therefore an opportunity for investors to cater to the remaining 70 percent.

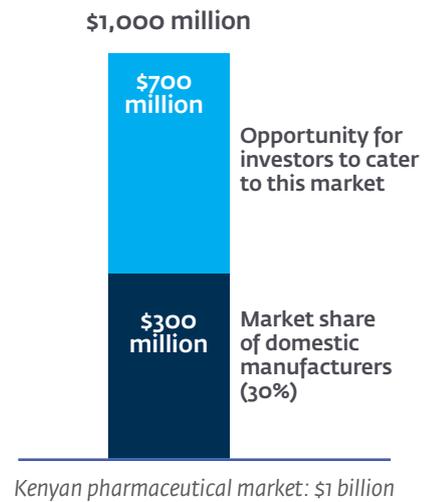
#### Export market

Export markets could drive the growth of Kenya's pharmaceutical industry. 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 currently 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 would translate to exports worth \$678 million.

#### Therapeutic area

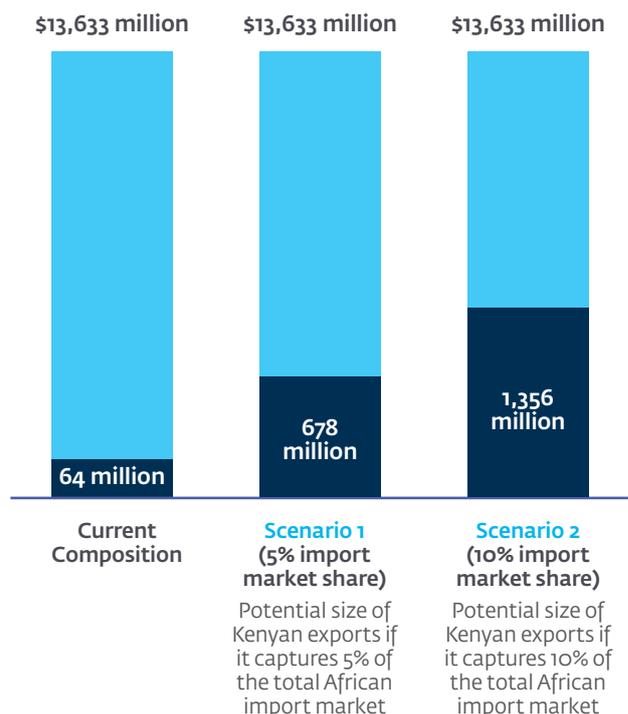
According to the EAC Plan of Action, domestic pharmaceutical manufacturers have a strong presence in anti-infective product categories such as cough and cold preparations, antiprotozoals, antiseptics, antiasthmatics, and antibiotics. However, there is also a huge demand for immunological and cardiovascular 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 2: DOMESTIC PHARMACEUTICAL OPPORTUNITY FOR INVESTORS**



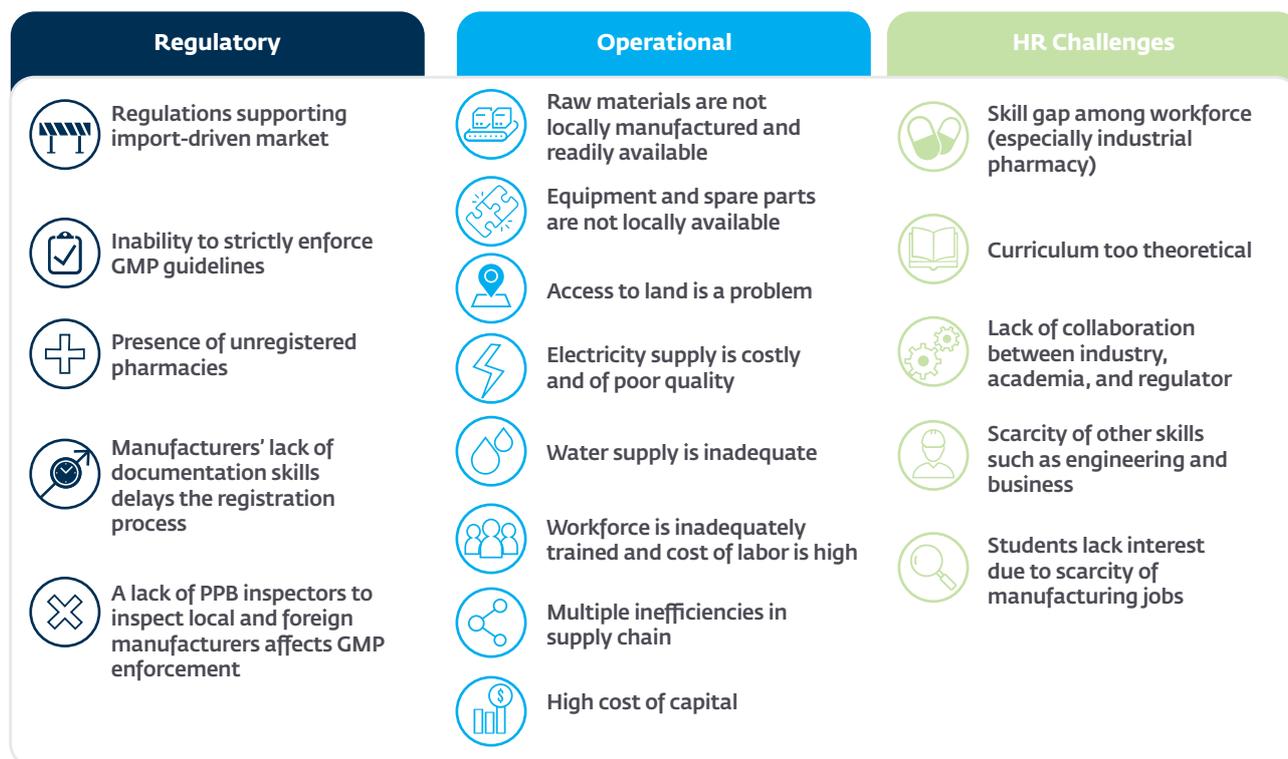
*Kenya has a well-developed health sector and manufacturing industry, with the capacity to manufacture some health products (medicines and associated medical consumables) for both internal and export markets.*

**FIGURE 3: EXPORT OPPORTUNITY SIZE AND SCENARIOS FOR INVESTORS**



## Challenges

**FIGURE 4: SUMMARY OF CHALLENGES AFFECTING INDUSTRY PLAYERS**



## RECOMMENDATIONS

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

### 1. Develop a national 10-year strategic plan to develop 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 into a competitive regional hub for manufacturing pharmaceutical products by 2030, including drug formulations for noncommunicable diseases, active pharmaceutical ingredients, excipients, and veterinary medicines.

### 2. 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. It is necessary to:

- Strengthen the pharmaceutical sector agenda and representation in the National Investment Council, particularly 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 in the National Investment Council.

### 3. Legal landscape

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

- Create a multisectoral committee to own and facilitate the review and implementation of laws targeting Kenya's manufacturing industry (especially for health products).
- Set a clear timeline (possibly every five years) 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.
- Government to monitor and advocate for laws and policies in the EAC and COMESA trading blocs that do not restrict its exports.
- Harmonize investment laws in Kenya and position the country to benefit from the African Continental Free Trade Area and other priority regional economic communities.

#### 4. Regulatory landscape

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

- Develop an Inclusive Coordination Framework to harmonize the regulation of the pharmaceutical industry and ensure adequate involvement and representation of the sector.
- Implement existing regulatory policies, and measure and report on performance to the relevant Senate and House subcommittees via the National Investment Council, including on regulation of the manufacturing and retail pharmacy subsectors.
- Clarify the roles and responsibilities of the National Quality Control Laboratory (NQCL) and the Pharmacy and Poisons Board (PPB) 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 action.
- Design policies to incentivize and support manufacturers achieving World Health Organization (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.

#### 5. Human resources

There are skill gaps in Kenya's workforce. 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:

- Policymakers and education specialists need to adjust education curricula to ensure that skills in the workforce meet industry needs.

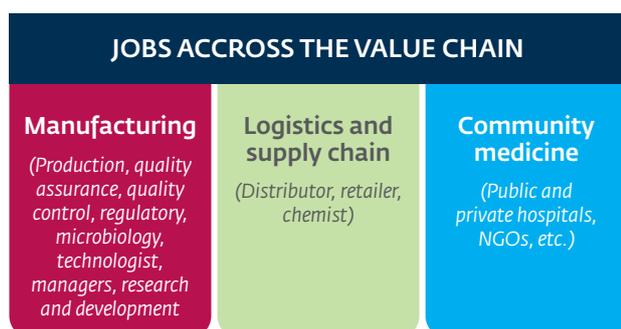
- Metrics need to be developed to measure outputs and outcomes of internships and on-the-job training. This will help incentivize the private sector to invest in training programs for secondary and tertiary levels of education to nurture talent that can drive innovation.

#### 6. Operational landscape

Operational challenges affecting domestic pharmaceutical manufacturing include unreliable 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. 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 ecofriendly common effluent treatment plants. This could be facilitated by making available common user facilities in special economic zones, export processing zones, 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 and excipients.

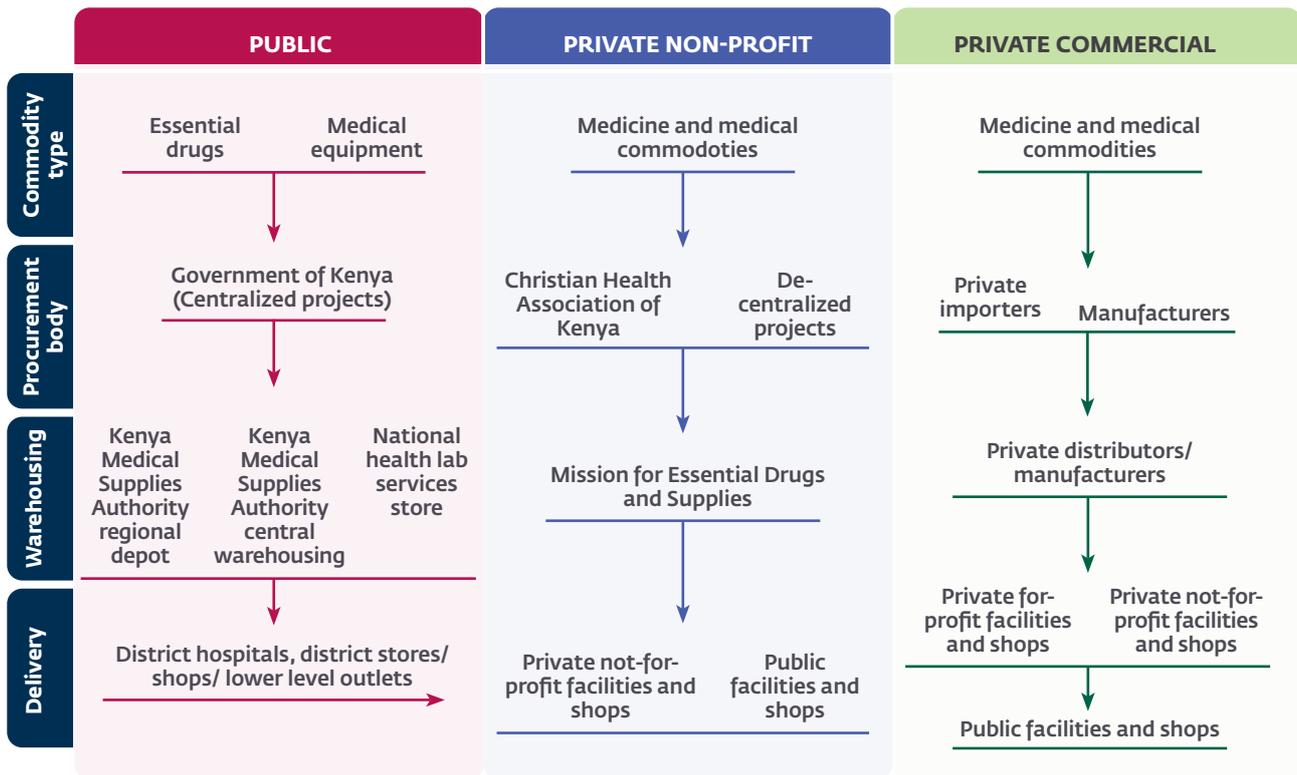
**FIGURE 5: POSSIBLE JOB OPPORTUNITIES FOR THE PHARMACY GRADUATE**



#### 7. Research and development

Currently, the maturity level of pharmaceutical manufacturing in Kenya is Level 1. The 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:

**FIGURE 6: KENYA PHARMACEUTICAL SUPPLY CHAIN**



- 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.

### 8. 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.

### 9. 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.**



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