

KENYA





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**PHARMACEUTICALS
INVESTMENT PROFILE**

KENYA

2020

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Under MA, PIGA aims to contribute to job creation and sustainable growth in Ethiopia, Kenya, Mozambique and Zambia by supporting these countries to attract foreign direct investment, specifically Chinese investment, in the agro-processing and light manufacturing sectors. PIGA is also designed to enhance the capacity of these countries for effective investment promotion.

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ACRONYMS AND ABBREVIATIONS

Unless otherwise specified, all references to dollars (\$) are to United States dollars, and all references to tons are to metric tons.

AfCFTA	African Continental Free Trade Area	KPLC	Kenya Power and Lighting Company
AGOA	African Growth Opportunity Act	KRA	Kenya Revenue Authority
CBK	Central Bank of Kenya	KSh	Kenyan shillings
CIF	Cost, insurance and freight	MEDS	Mission for Essential Drugs and Supplies
COMESA	Common Market for Eastern and Southern Africa	NEMA	National Environment Management Authority
CPI	Consumer Price Index	PIN	Personal identification number
EAC	East Africa Community	PPB	Pharmacy and Poisons Board
EIA	Environmental impact assessment	PPI	Price Producer Index
EPZ	Export processing zone	PQ	Pre-qualification
FDI	Foreign direct investment	R&D	Research and development
GDP	Gross domestic product	SEZ	Special Economic Zone
GMP	Good Manufacturing Practices	SGR	Standard gauge railway
GSP	Generalized System Preferences	TEUs	Twenty-foot equivalent units
ICT	Information and communications technology	UHC	Universal Health Coverage
JKIA	Jomo Kenyatta International Airport	UNIDO	United Nations Industrial Development Organization
KEMRI	Kenya Medical Research Institute	WHO	World Health Organization
KEMSA	Medical Supplies Authority	WTO	World Trade Organization
KNBS	Kenya National Bureau of Statistics		



Kenya: Country overview

The Republic of Kenya is located on the eastern coast of Africa along the Indian Ocean.

Its geographical neighbours are the United Republic of Tanzania to the south, the Republic of Uganda to the west, the Republic of South Sudan to the north-west, the Federal Democratic Republic of Ethiopia to the north and the Federal Republic of Somalia to the east.

Kenya is a mature democracy and has enjoyed political and economic stability since independence. In 2010, the country promulgated a new constitution that brought with it a robust and independent judiciary, a bicameral legislature and devolution with a national government and 47 semi-autonomous counties governed by elected governors. In Sub-Saharan Africa, Kenya is the 5th largest economy, with strong growth prospects supported by an emerging urban middle-class population with an increasing appetite for high-value goods and services. It is the dominant economy in the East African Community (EAC), contributing more than 40% of the region's gross domestic product (GDP).

The country's development blueprint, Vision 2030, launched in 2008, aims to transform Kenya into a newly industrialized, middle-income country providing a high quality of life to all its citizens by 2030 in a clean and secure environment. In the last 10 years, significant progress has been made in fulfilling this vision. In order to accelerate the achievement of the aspiration of Vision 2030, President Uhuru Kenyatta conceptualized and launched the Big Four Agenda in 2017, focusing on four priority sectors of the government until 2022: manufacturing, food security, affordable housing and universal health coverage.

Table 1: Key facts

Capital city:	Nairobi
Area:	582,646 km ²
Population:	47.56 million
Population growth:	2.2%
Working age population:	25 million
Literacy rate (15+ years):	81.5%
GDP:	\$89.05 billion (2018)
GDP growth:	6.3% (2018)
GDP per capita:	\$1,863 (2018)
FDI inflow:	\$1.6 billion (2018)
FDI growth:	26% (2018)
Total exports:	\$613 billion (2018)
Total imports:	\$1.76 trillion (2018)
Currency:	Kenyan shilling
Exchange rate (per USD):	KSh 101.9

Sources: KenInvest, Ministry of Agriculture, World Investment Report – UNCTAD, World Bank, 2019.



Figure 1: Map of Kenya



Source: <https://thecommonwealth.org/our-member-countries/kenya>.

The population of Kenya in 2019 was 47.6 million, having increased by 2.2% annually from 2009.¹ Nearly 70% of the population is below 35 years of age, presenting a youthful and skilled manpower to drive the country's industrial growth.²

POLITICAL CONTEXT

Kenya has maintained remarkable political stability since independence in 1963. The current constitution, put into effect in 2010, creates a decentralized system of government with two levels: the national and county governments. Resources management and representation is delegated to a lower level, from the central government to the local level. Institutions have been established to operationalize this system of governance. This constitution provides for separation of powers between the legislature, judiciary and executive and provides a system of checks and balances. The government considers the private sector as the engine of economic development.



Climate in Kenya

Kenya's climate varies by location.

Coastal region: Warm and humid with temperatures ranging from 20°–30°C, with rainfall most of the year.

Savannah grasslands: Wildlife-rich landscapes cover a large part of Kenya, and are hot and dry, with short rains and long drought.

Rift Valley and Central Highlands: Cool/cold climate, temperatures ranging from 10°–28°C.

North and east regions: Mainly arid and semi-arid.

Western Kenya: The Lake Victoria region is mostly hot and humid with rainfall throughout the year.

Source: KenInvest. Investor Guide for Kenya; Agroprocessing and light manufacturing sectors, 2018.

¹ <https://www.centralbank.go.ke/shareholding-information/> and <https://www.kba.co.ke/members.php>.

² <https://www.ira.go.ke/index.php/licenced-insurers>.

STRATEGIC LOCATION AND INFRASTRUCTURE

With a border to the Indian Ocean, Kenya is a strategic gateway to Eastern and Central Africa, the Middle East, Asia, Europe and the rest of the world. The Port of Mombasa, Kenya's principal seaport, is the largest port in the region and provides direct connectivity to more than 80 ports worldwide. Mombasa is linked to Uganda, the Republic of Rwanda, the Republic of Burundi, the Democratic Republic of the Congo, Tanzania, South Sudan, Somalia and Ethiopia by road. The geographic location makes Kenya ideal for partnerships aimed at enlarging regional and global market share.

A railway line also runs from the Port of Mombasa to the interior, Uganda and northern Tanzania. Kenya is upgrading the railway capacity to handle 50% of freight cargo from the port by developing a standard gauge railway (SGR) line between Mombasa and Nairobi with connectivity to Uganda. Furthermore, Kenya has the largest aviation infrastructure in the East African Community (EAC) region with five international airports. The aviation industry propels other sectors such as tourism, manufacturing, horticulture and hotel industries, which contribute greatly to Kenya's economy.

INDUSTRIAL DEVELOPMENT OVERVIEW

Kenya has adopted industrialization as the means to transform its economy. The industrial development strategy is aligned to Vision 2030, the national long-term development blueprint that was launched in 2008 to transform Kenya into a newly industrialized, middle-income country. Progress has been achieved in implementation of this vision by the government through successive five-year medium-term plans (MTP).

The third MTP focuses on delivering the Big Four Agenda, which defines the government priorities for the 2018/22 planning cycle, and this includes food security, affordable housing, manufacturing, and affordable healthcare for all. The anticipated role of the manufacturing sector is to create employment and to increase its contribution to the gross domestic product (GDP) by at least 15% per annum.^{3, 4} The pharmaceutical manufacturing industry is crucial in the realization of the Big Four Agenda, as the Kenya Pharmaceutical Policy aims to improve access to medicines by expanding local production.

Kenya is currently the leading producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region and the 3rd largest exporter of pharmaceuticals in Africa. The pharmaceutical industry in Kenya supplies approximately one-quarter of the local market.⁵ The United Nations Industrial Development Organization (UNIDO) has provided advisory and capacity building support to local pharmaceutical production in Kenya. In 2012, UNIDO, in partnership with the Ministry of Industrialization, the Ministry of Medical Services, Pharmacy and Poisons Board and the Federation of Kenya Pharmaceutical Manufacturers, established the Kenya Pharmaceutical Sector Development Strategy, presently being implemented to enable Kenya to develop a viable pharmaceutical industry producing quality medicines for the domestic and export markets.⁶ The contribution of the pharmaceutical industry to the GDP was 1.22% in 2017.



MODULE 1: WHY INVEST IN KENYA?

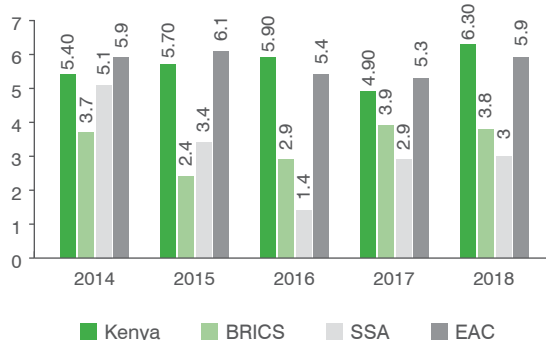
1.1. THRIVING ECONOMY

Kenya is classified as a lower-middle income country with a GDP of \$87.9 billion (2018) with a ~5.1% growth in 2019. It is the largest economy in the EAC and constitutes approximately 40% of the total EAC GDP. It is a vibrant economy experiencing continued infrastructural improvements that include roads, railways and the increasing connectivity of the international airport linking Kenya to the world and business opportunities.

a) Economic outlook – growth

Kenya is a diversified economy and continues to enjoy good economic growth, supported by a relatively stable macroeconomic environment. The real gross GDP has been on a steady growth path at an average of ~5% year on year since 2012. In 2018, the real GDP was 6.3% up from 4.9% in 2017. In terms of current prices, the GDP increased by 9.3% from \$81.4 billion in 2017 to ~\$89 billion in 2018.

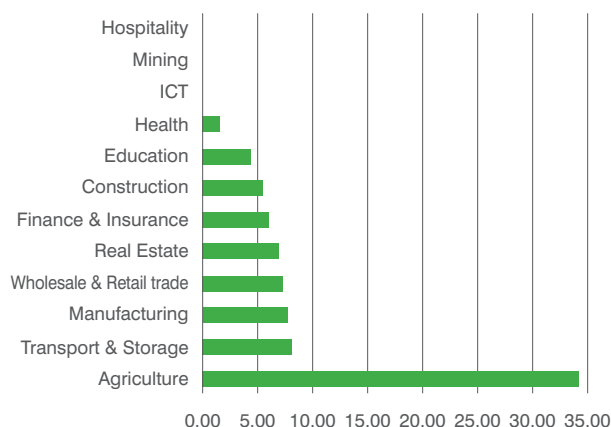
Figure 2: Kenya's GDP growth rate (2014–18)



Source: KNBS Economic Survey, 2018.

This was supported by several sectors, with agriculture accounting for one-third (34.2%) of the total value of the economy. Other notable contributing sectors include transportation and storage and manufacturing at 8% and 7.7% respectively. The broad-based economic growth for 2018–20 is projected at an average of 6%, outperforming the 5.6% for the previous five years (2013–17).

Figure 3: Sectoral contribution to GDP (2018)



Source: KNBS Economic Survey, 2018.

b) Foreign direct investment

Kenya is known for its liberal approach to economic development and supports trade devoid of price and exchange controls. It is the 2nd largest foreign direct investment (FDI) recipient in East Africa after Ethiopia. In 2018, FDI flows in Kenya increased by 33% to approximately \$1.6 billion from \$1.2 billion in 2017. This was channelled into several industries, mainly chemicals, manufacturing, oil and gas, information and communications technology (ICT), banking and infrastructure. The leading nations with FDI to Kenya are the People's Republic of China, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

The country has been keen to create an accommodating investment environment in order to attract FDI and increase private sector development and growth in general. This is verified by the government's effort to privatize some state-owned enterprises in a bid to increase efficiencies and demonstrate Kenya's commitment to improving the environment for private sector investors. In addition, a robust legal framework exists to streamline business in Kenya, thus making it easier for entities to establish a presence and operate. Furthermore, capital repatriation and remittance of dividends out of the country is not restricted. Kenya's improved Ease of Doing Business ranking has also made it attractive to investors. Kenya was ranked 61st amongst 190 countries in the World Bank Ease of Doing Business rating in 2018, up from 80th position in 2017.

c) Inflation

Sound monetary policy, driven by an independent Central Bank of Kenya (CBK), has restored stability in the currency markets and the financial sector in general as exemplified by the contained average inflation rate of 4.7% in 2018, down from 8% in 2017. The inflation for 2019 was at 5.8% and has averaged 6.38% in the last six years (2014–19). The capping of the interest rate at 14% by the CBK in 2016 contributed significantly to decelerated inflation. The CBK Monetary Policy Committee has also helped to ensure that the Kenyan shilling stabilizes against major trading currencies; an effort (see next section) that has led to the shilling recently gaining against major currencies.

d) Interest rates

The interest rate has remained largely stable, partly due to capping of the interest rate. The CBK lowered the Central Bank Rate (CBR) twice in 2018, to 9.5% as at end of March 2018 and down to 9% in July 2018. The interbank rate rose to 8.15% in December 2018 from 7.27% in December 2017.

e) Banking sector profile

Kenya has 42 licensed commercial banks (two under statutory management and receivership), 13 microfinance banks, one mortgage finance company, 3 credit reference bureaus, 8 authorized non-operating bank holding companies, 9 representative offices of foreign banks and 73 foreign exchange bureaus (Central Bank of Kenya).

According to the 2019 FinAccess Household Survey report, access to financial services and products in Kenya has steadily improved from 27% in 2006 to 75% in 2016 to 83% in 2019 due to uptake of mobile money, adoption of transformative financial technologies, innovations, and government initiatives and policies.

Commercial banks' interest rates on loans and advances declined to 12.51% in December 2018 from 13.64% in 2017. As such, the loan–deposit interest spread narrowed marginally from 5.41% in December 2017 to 5.09% in December 2018. Kenya monetary policy supports non-inflationary credit expansion space, which is critical for growth of key sectors of the economy while promoting stability in the foreign exchange market.

The overall commercial banks' credit grew by 5.9% from KSh 3,344.9 billion in 2017 to KSh 3,543.9 billion in 2018. Credit advanced to various sectors of the economy increased, and this included the manufacturing sector (6.5%), and wholesale and retail trade, hotels and restaurants increased by a combined 2.9%. Commercial banks' credit to the public sector expanded by 16.9% and this was largely government securities. Overall, loans and advances increased by 12% to KSh 358.6 billion in 2018 from KSh 320.5 billion in 2017. Capital reserves increased by 19.3% to KSh 107.1 billion in 2018.

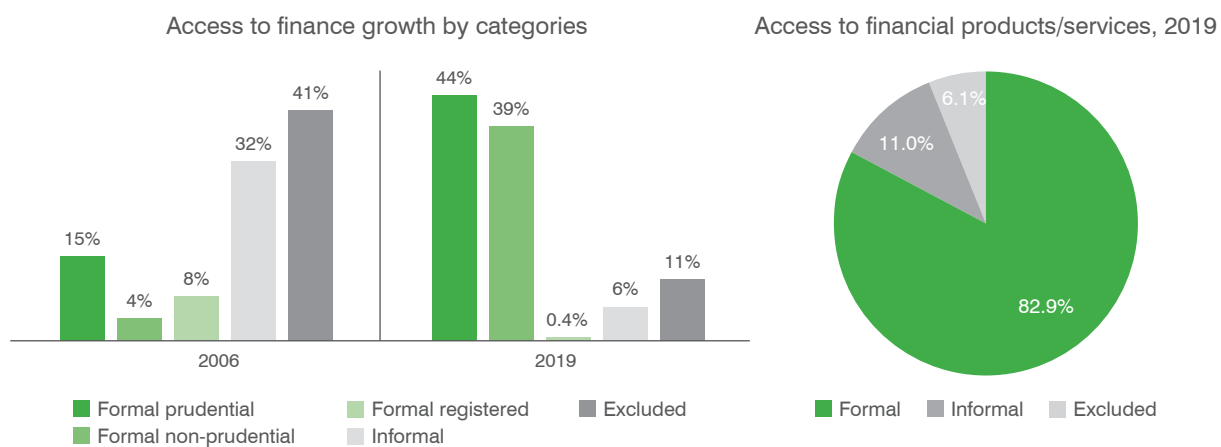
The Banking Act (2016) that capped interest rates at CBK lending rate +4% was repealed in October 2019, allowing the banking sector to self-regulate their interest rates. This is likely to spur further growth of loans by commercial banks to various sectors, especially the small and medium-sized enterprises (SMEs).

f) Trade statistics

The overall volume of trade in Kenya increased by 17.7% in 2018 compared to a 15.4% increase in 2017 buoyed by 11.4% growth (valued at KSh 180.9 billion) in exports to Asia that accounted for 29.5% of the total exports in 2018. Exports to the Republic of India, China, the Kingdom of Thailand and the Islamic Republic of Afghanistan rose by 5.5% and accounted for 64.8% of all export earnings from Asia. Leading export products in 2018 were tea, horticulture, articles of apparel and clothing accessories, coffee, titanium ores and concentrates that cumulatively accounted for 62% of the total domestic export earnings. On the other hand, imports expenditure increased to 1,760.2 billion in 2018 from KSh 1,725.6 billion in 2017, while total export earnings grew marginally from KSh 594 billion in 2017 to KSh 613 billion in 2018.

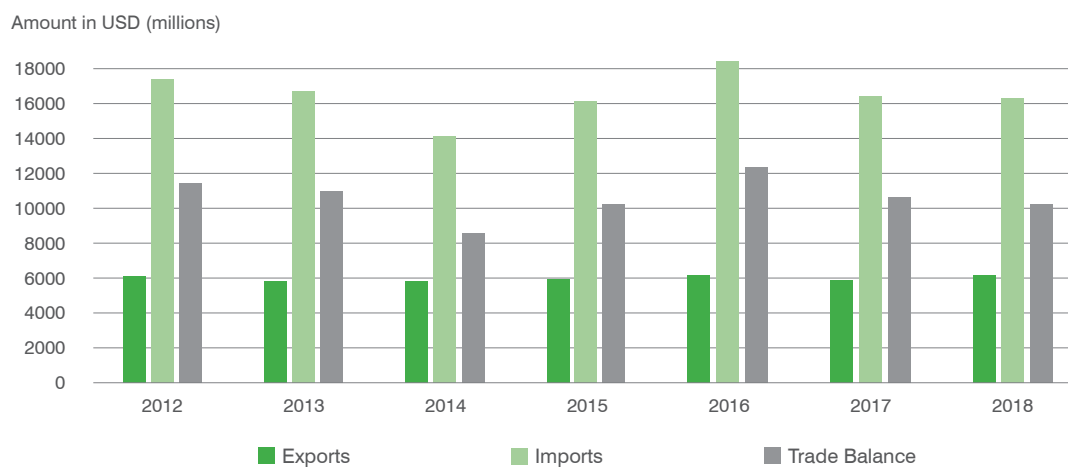
Kenya's key export markets are Uganda, the Islamic Republic of Pakistan, the United States of America, the Netherlands, the United Kingdom, the United Arab Emirates, Tanzania, the Arab Republic of Egypt, and Rwanda. See Section 1.7 and 2.2. for pharmaceuticals trade information.

Figure 4: Access to financial products and services statistics



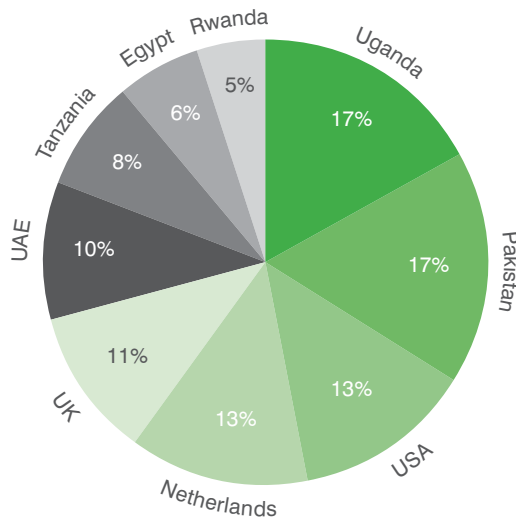
Source: 2019 FinAccess Household Survey report, CBK, Kenya.

Figure 5: Kenya's export and import products (2012-18)



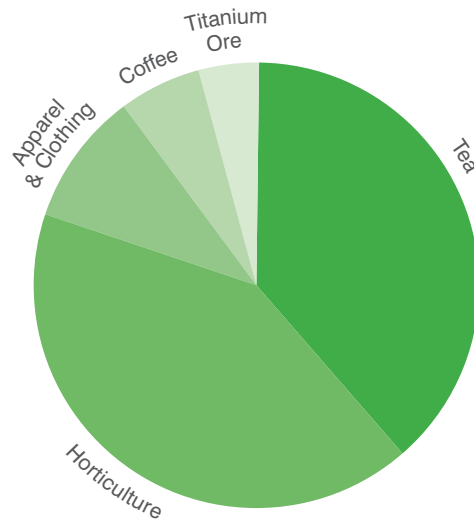
Source: KNBS Economic Survey, 2018.

Figure 6: Kenya's key export markets



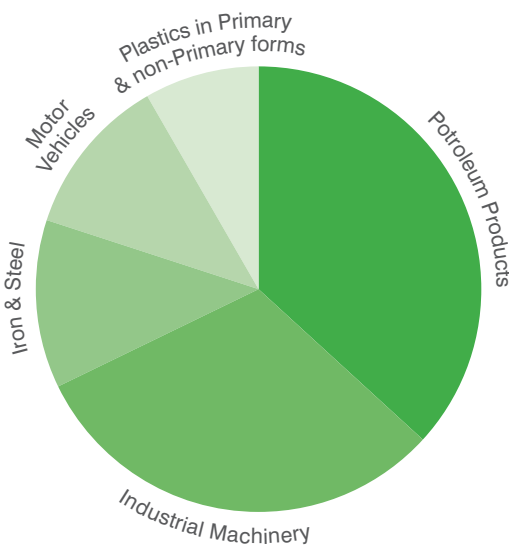
Source: KNBS Economic Survey, 2018.

Figure 7: Kenya's top export products (2018)



Source: KNBS Economic Survey, 2018.

Figure 8: Kenya's top import products (2018)



Source: KNBS Economic Survey, 2018.

Total exports earnings increased by 3.2% to KSh 613 billion in 2018, while imports rose by 2% to KSh 1,760 billion in the same period. This widened the trade balance by 1.4% to a deficit of KSh 1,147.3 billion in 2018 from a deficit of KSh 1,131.5 billion in 2017. Top import products were petroleum products (16.8%), industrial machinery (14.4%), iron and steel (5.6%), road motor vehicles (5.3%), plastics in primary form and non-primary forms (3.9%) and pharmaceutical products (3.4%), all accounting for 49.4% of total imports in 2018. The Kenyan shilling appreciated against major trading currencies in 2018 compared to 2017 based on the Overall Trade Weighted Index, which was 115.7 in 2018 and 116.5 in 2017. The shilling strengthened against the US dollar and the Japanese yen but weakened against the euro and sterling pound. The shilling has shown resilience and is expected to remain stable owing to the country's macroeconomic factors.

Table 2: Balance of trade (billions, 2014–18)

DESCRIPTION	2014	2015	2016	2017	2018
Exports (FOB):	460 572	499 708	506 548	530 617	541 469
Domestic exports	76 664	81 337	71 519	63 511	71 459
Re-exports					
Total exports	537 236	581 045	578 067	594 128	612 928
Imports (CIF):	1 599 619	1 540 731	1 389 741	1 671 724	1 700 812
Commercial	18 703	36 826	42 014	53 899	59 409
government					
Total imports	1 618 322	1 577 557	1 431 755	1 725 623	1 760 221
Balance of trade	(1 081 085)	(99 512)	(853 688)	(1 131 494)	(1 147 293)

Source: KNBS Economic Survey, 2018.

Table 3: Foreign exchange rates of the Kenyan shilling for selected currencies (2014-18)

CURRENCY	2014	2015	2016	2017	2018
1 Euro	116.84	108.96	112.33	116.73	119.63
1 US dollar	87.92	98.18	101.50	103.41	101.29
1 Pound sterling	144.88	150.17	137.66	133.20	135.25
1 Chinese yuan	14.27	15.62	15.29	15.30	15.33
100 Japanese yen	83.26	81.12	93.55	92.22	91.74

Source: KNBS Economic Survey, 2018.

g) Improved business environment

The Kenyan Government has set policies to support economic development. In addition, presidential roundtable dialogues with the private sector, mainly from the manufacturing industries, are held to address issues of concern to the private sector for the overall improvement of doing business in Kenya. There are also sector-led discussions at ministerial level that seek to fast track policies to enable a conducive environment for business. These interventions steered the establishment of a one-stop shop service delivery by Kenya Investment Authorities that provides timely government services for investors and also eliminates delays where inspections are required for licensing.

The automation of government processes through the eCitizen portal and the Huduma Centres across the country provide efficient service delivery to citizens and investors. For visa applications, Kenya has an online application system that allows business travellers to obtain an e-visa that is validated upon arrival.

In addition, Kenya has a pre-export verification of conformity (PVOC) process for all imports to ensure that goods meet mandatory safety, quality and security requirements. This process makes international trade seamless, helps to avoid delays in

Customs and reduces potential losses arising from importation of non-compliant products. Actualization of the current presidential Big Four Agenda impacts positively on the business environment. It gives priority to four main sectors, namely housing, food security (agribusiness), manufacturing and health (universal health coverage (UHC)).

1.2. MODERN LABOUR SYSTEM

Kenya has a large pool of highly educated workforce with approximately half a billion students being enrolled in local universities annually. This provides a robust pipeline for future workforce. In addition, there is a considerable number of Kenyans who are trained in global institutions and bring the needed skills into the economy. The government invests in education of its citizenry. For instance, the total expenditure for the Ministry of Education was increased by approximately 6.5% to KSh 439 billion in FY 2018/19.

The government has invested in the development of blue-collar job skills, such as electricals, plumbing and construction, which are essential for the current developmental agenda. The government has also increased the number of educational institutions across all categories, especially the public vocational

training centres (technical vocational education and training (TVET) institutions) that grew by 26.6% to 1,502 in 2018. The TVET subsector aims to provide relevant competencies in strategic disciplines by 2020 for spurring industrial and economic development in line with Vision 2030. However, there are no training institutions for specific skills in pharmaceutical manufacturing. Most pharmaceutical trainings are provided through pharmacy departments in the high academic institutions. This remains an area needing investment. The government has also extended educational loans to students in this category. Two additional universities were chartered in the same period, increasing the number to 63. As such, Kenya has a high literacy rate of 82% for the population of age group 15 and older (UNESCO Education indicators) and approximately 55% of the 47 million population are in the working age group of 15–64 years. In 2018/19, Kenya launched the National Education Management Information System (NEMIS), a digital data management solution meant to track performance and registration for all primary and secondary school students and teachers in order to ensure efficiency and effectiveness in the sector.

The government partners with the Kenya Private Sector Alliance (KEPSA) and the World Bank to improve the employability of graduates through the employability programme that was initiated in 2011. The project focuses on private sector internships, training (by KEPSA) and institutional capacity building to produce graduates with the required skills for the market. In 2018, the labour force participation rate for Kenya was 66.3% according to the World Bank report and is expected to remain the same. This gives investors access to a pipeline of professionals with various skill sets at competitive wages. Employment in Kenya is governed by the Employment Act of 2007, Labour Relations Act, Work Injury Act and Occupational Health and Safety Act (PIGA document). The legal instruments are interpreted and enforced by the Employment and Labour Relations Court in Kenya.

The labour market is well structured, enabling employees to be hired on different terms; that is, consultancies, contracts, fixed-term employment or permanent employment. In terms of remuneration, the government has set minimum wages for low-level workers (Table 4). Employers are also required to remit taxes and other mandatory payments to statutory bodies of government once the service of an employee is enlisted. These include the National Hospital Insurance Fund and the National Social Security Fund for national health insurance and retirement benefits purposes, respectively.



Table 4: Select monthly basic minimum wages information (KES)

Occupation	NBI, MBA, KISM*	NBI environs	Other areas
General labour	13 573	12 523	7 241
Receptionist/storekeeper/clerk	20 905	19 112	16 295
Machine attendant	15 382	14 315	11 603
Night watchman	15 142	14 038	8 636
Heavy commercial drivers/salesmen drivers/cashier	30 627	28 822	27 024
Artisans I	30 627	28 822	27 024
II	24 884	23 731	21 418
III	23 039	21 175	18 845
Machine operator/light van drivers	18 320	16 908	13 975
*NBI, Nairobi; MBA, Mombasa; KISM, Kisumu			

Source: Kenya Subsidiary Legislation of 2018 on basic minimum monthly wage (excludes house allowance).

1.3. IMPROVING INFRASTRUCTURE AND STRATEGIC GEOGRAPHICAL LOCATION

The Government of Kenya recognizes the importance of infrastructure as the backbone of economic development and is investing heavily in several infrastructures, which include energy, roads, rail, ports, airports, and information and communications technology (ICT).

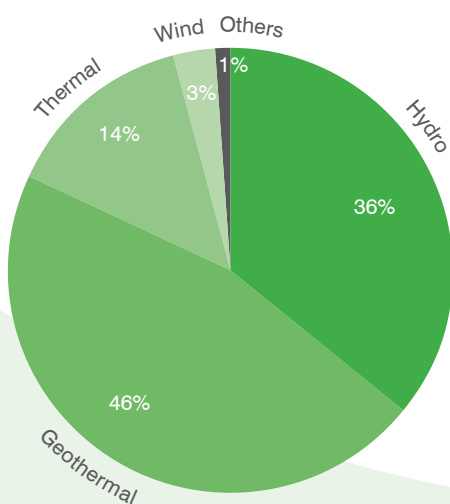
ELECTRICITY AND WATER OVERVIEW

Kenya has a stable power supply and continues to invest in electricity generation projects, with the latest being the Garissa solar power plant and Turkana wind power plant. Kenya's power generation comprises renewable energy (86%) and thermal generation (14%).

Generation and distribution of electricity is carried out by state-owned enterprises, namely Kenya Electricity Generating Company PLC (KenGen) and Kenya Power and Lighting Company PLC (KPLC). KenGen is the largest producer, covering approximately 80%, and the rest is obtained from independent power producers (IPPs). The electricity generation capacity was 2,351 MW in 2018 (KPLC annual report, 2018) against a demand of 1,802 MW. In 2018, the World Bank approved a \$180 million guarantee to the private sector for mobilization of private sector funding to improve energy production through KenGen.

Kenya is also working to improve availability, reliability and quality of water resources as per the National Water Master Plan 2030 launched on 26 March 2014.

Figure 9: Electricity generation sources (2018)



Source: KPLC.

Table 5: Electricity statistics (2018)

Category	Value
INSTALLED CAPACITY (MW)	2 712
Effective capacity (MW)	2 638
Peak demand (MW)	1 802
Reserve margins grid (when all plants are available)	910
Energy purchased (2016–17) (GWh)	10 702
Number of customer accounts (millions)	6.5
Electricity access	75%
Transmission and distribution lines, circuit length in kilometres (132 kV)	5 485 circuit km (2017)

Source: KPLC, Kenya Electricity Transmission Company (KETRACO), World Bank Report.

Table 6: Electricity costs in Kenya (2018)

	VOLTAGE (V)	Charges per unit consumed	Demand charge per KVA
Commercial	415	12.00	800
	11 000	10.90	520
	33 000	10.60	270
	66 000	10.30	220
	132 000	10.10	220
	240	12.00–15.80	-
Domestic	240	12.00–15.80	-

Note: Values are in KES (fixed costs were scrapped as of August 2018 as per the new tariff guide).

Source: KPLC.

Table 7: Water tariffs in various towns

Water tariffs	Nairobi	Mombasa	Kisumu	Naivasha
Deposit	\$500	\$300–\$1000	\$300	\$100–\$200
Connection	\$150	\$25	\$150	-
Water rates	>60M ³ : \$0.6/M ³	>300M ³ : 2.0/M ³	300M ³ : \$1.6/M ³	>60M ³ : \$1.5/M ³
Sewerage tariff (as % of water billed)	75%	75%	77%	75%

Note: Only industrial table relevant water/sewerage rates included.

Source: Water tariffs:

- <https://www.nairobiwater.co.ke/index.php/en/watertariffs>
- <http://www.mombasawater.co.ke/index.php/customer-care/water-and-other-services-tariffs>
- <https://www.kiwasco.co.ke/downloads/>
- <https://www.naivashawater.co.ke/wp-content/uploads/2018/09/CATEGORIES-TARIFFS.pdf> (Accessed 13/05/2020)

Source: <https://www.safaritravelplus.com/images/cities/nairobi-city/>.

MODERN ROAD NETWORKS

Kenya has approximately 177,800km of roads. Only 63,575km of this road network is classified. However, Kenya is expanding the classified roads at a rate of ~600km annually, with a projected road expansion expenditure of approximately KSh 197 billion for FY 2018/19. This includes in-country (counties and national) and regional connecting roads that cut across the EAC region. These cross-border roads have enhanced Kenya's position as a gateway and a transport hub to the East African and the Great Lakes region. For instance, the Lamu Port, South Sudan, Ethiopia Transport Corridor (LAPSSET) project is opening a transport corridor covering not only rail and oil pipeline, but also road from Lamu in Kenya to Ethiopia and South Sudan. This is advantageous to the business community.

Table 8: Classified road network data (2018)

TOTAL ROAD NETWORK (KM)	177 800
International trunk roads (A)	3 618.31
National roads (B)	2 681.90
Primary roads (C)	7 995.59
Secondary roads (D)	11 049.39
Minor roads (E)	26 906.31
Special purpose roads	11 322.98
All classes	63 574.48

Source: Kenya National Highways Authority (KENHA).

RAIL, PORTS AND AIRPORTS

Kenya's infrastructure is undergoing significant transformation as evidenced by the recently completed 480km SGR line from Mombasa to Nairobi. The high-speed SGR is set to ease congestion on the roads, shorten travel time for passengers and boost the economy. A further 120km has been finalized and connects Nairobi to Naivasha. This will activate the proposed dry port to be stationed in Naivasha town and reduce transportation costs, especially into the EAC region. In 2018, SGR contributed to the rail freight performance that saw a threefold increase from 1.1 million tons in the previous year to 3.5 million tons due to the SGR service line. This infrastructure is vital for trade growth in Kenya and serves as the gateway to the vibrant EAC region.

Kenya has also upgraded sea ports in the country over the years in a bid to improve services, with a focus on system changes in order to streamline clearance processes and other services. In 2018, the cargo handling at the Port of Mombasa improved by 2% to 30.9 million tons. Additionally, the port handled total cargo equivalent to 1.3 million twenty-foot equivalent units (TEUs), making it one of the top eight busiest ports in Africa and the largest in the EAC region. Integration of Mombasa port services, Naivasha dry port and Lamu port will further increase logistic efficiencies.

Airports are essential for economic development. Kenya has five main airports: Jomo Kenyatta International Airport (JKIA), Mombasa, Kisumu, Eldoret and Isiolo airports – these are complemented by eight airstrips. Nairobi is the regional aviation hub. Nairobi's JKIA is one of the busiest airports in Africa, with destinations in more than 50 countries across the globe. The US Federal Aviation Administration has granted Kenya Category 1 rating, paving the way for direct flights to the United States of America. In 2018, Kenyan airports handled approximately 12 million passengers, up from 10.1 million in 2017.

Table 9: Passenger traffic (millions) in Kenya (2018)

Airport	Domestic	International
JKIA	2018: 1 672 2017: 1 476	2018: 6 346 2017: 5 795
MIA	2018: 1 005 2017: 944	2018: 486 2017: 302
Others	2018: 2 196 2017: 1 577	2018: 47 2017: 24
TOTAL	2018: 4 873 2017: 3 997	2018: 6 879 2017: 6 121

Source: KNBS.



1.4. ECONOMIC AND TRADE COOPERATION

Kenya is a signatory to several regional economic and trade cooperations in Africa and globally. This ranges from bilateral trade agreements to multilateral trade agreements. Some of the major trade cooperations include the EAC and COMESA regional blocs, African Growth and Opportunity Act (AGOA) and World Trade Organization (WTO). Kenya was amongst the first countries to sign the African Continental Free Trade Area (AfCFTA) agreement, which became effective in May 2019 (<https://www.tralac.org/resources/our-resources/6730-continental-free-trade-area-cfta.html>). The AfCFTA agreement opens access to a 1.2 billion population market with an estimated consumer expenditure of ~\$2.1 trillion by 2025 (Mckinsey Report, 2016).⁷ The pharmaceutical market can also be accessed through AfCFTA arrangements that advance free continental market for goods and services.

All these cooperations facilitate and enhance trade between Kenya and the partner states.

The EAC is also working on implementing a single Customs territory that will further improve market access and trading in the region. The EAC trade zone, with six member states, has a population of 150 million and an estimated market value of \$150 billion, with the pharma market being approximately \$1.74 billion.⁸ The COMESA trade zone comprises 21 member states with a population of ~650 million and a market size of \$768 billion (pharma market estimated at ~\$7 billion). Under the African Growth and Opportunity Act (AGOA), Kenya qualifies for duty-free access to the US market for their apparel, textile and handicraft products until 2025. The United States is home to approximately 330 million people with a market value of approximately \$19 trillion.

Other trade agreements include the African, Caribbean and Pacific (ACP/Cotonou Partnership Agreement and Generalized System of Preferences (GSP)). Under the ACP, exports from Kenya to the European Union (EU) get duty-free entry of all industrial products as well as a wide range of agricultural products such as beef, fish, dairy products, cereals, fruits and vegetables. Under the GSP, a wide range of Kenya's manufactured products get preferential duty treatment in the United States, Japan, Canada, the Swiss Confederation (Switzerland), the Kingdom of Norway, the Kingdom of Sweden, the Republic of Finland, Australia, the Republic of Austria, New Zealand and most East European countries. Notably, no quantitative restrictions are applicable to Kenyan exports of any of the 3,000-plus items currently eligible for GSP treatment.⁹

Table 10: Value output and intermediate compensation (2018)

Year	Value of output	Intermediate consumption	Value added
2018*	2 407	1 718	689
2017	2 245	1 590	655
2016	2 132	1 477	654
2015	1 977	1 388	589
2014	1 820	1 282	538

Source: KNBS, 2018, *provisional.

In view of the above, Kenya presents a good opportunity for investors, as it is a true gateway to the continental market. Also, Kenya is home to many multinational companies, signifying a good business environment that investors could use to launch their Africa-wide initiatives.

MANUFACTURING SECTOR OVERVIEW

Manufacturing is a priority area in Kenya's economic development. The Big Four Agenda demonstrates a high level of commitment towards revitalizing the sector. Key industries include agroprocessing, textile, leather, paper, wood, metal and allied, automotive, oil and mining, ICT, plastics, chemicals and pharmaceuticals.

The manufacturing sector performed well in 2018 and grew by an overall 4.2% compared to 0.5% in 2017, driven mainly by agroprocessing, especially tea, coffee, sugar and dairy products. The growth is associated with the good rainy season that led to good crop harvests. Though the other sectors declined marginally, there was notable growth in the motor vehicle assembly (15.7%) and pharmaceutical production (14.1%). The latter is likely to have been spurred by the launch of the Universal Health Coverage (UHC) as part of the presidential Big Four Agenda.

Producer Price Index (PPI) dropped 0.51% year on year in the 4th quarter of 2019 on the back of a steady economic environment. The PPI for food products, electricity, paper/paper and wood/wood products decreased in 2019.

Employment in the manufacturing sector increased by 1.4% to approximately 308,000 jobs in 2018 and 18% of these are in the export processing zones (EPZs). Overall, the manufacturing sector value of output and intermediate compensation increased by 7.2% and 8% respectively in 2018.

1.5. INDUSTRIAL ZONES STRATEGY FOR INVESTMENTS

(Adapted from PIGA report 2017)

The manufacturing sector's role under Kenya's Vision 2030 is to create employment and wealth and to increase its contribution to the GDP by at least 10% per annum. Key targets have been set up to steer industrial growth, including the development of small and medium-sized enterprise (SME) parks, industrial and technology parks, and industrial manufacturing clusters. Kenya's industrial zones strategy is intended to cluster foreign investment in geographically defined areas. These can be found in special economic zones, e.g. the African economic zones, export processing zones, and public or private industrial parks. These parks facilitate setting up businesses in Kenya.

1) Export promotion zones (EPZs)

These are designated parts of Kenya that are aimed at promoting and facilitating export-oriented investments and developing an enabling environment for such investments. These zones are managed by the Export Processing Zones Authority (EPZA). EPZA's objective is to encourage and generate economic development, foreign direct investments and economic activities by encouraging foreign investment for the development of zones. This applies to the pharma sector too. Activities eligible for the EPZ incentives are:

- Zone developer/operator (the party that builds a zone, provides premises for investors to occupy and manages those premises);
- Enterprise (the party that undertakes the export-oriented investment activities, including: manufacturing and commercial activities such as bulk breaking, labelling, repacking and trading) (the 10-year tax holiday does not apply to commercial activities);
- Export-related service activities, including brokerage and repair, consulting and information, but excluding financial services.

These zones enjoy various incentives, namely:

- Ten-year corporate income tax holiday and a 25% tax rate for a further 10 years thereafter (except for EPZ commercial enterprises);
- Ten-year withholding tax holiday on dividends and other remittances to non-resident parties (except for EPZ commercial licence enterprises);
- Perpetual exemption from VAT and Customs import duty on inputs – raw materials, machinery, office equipment, certain petroleum fuel for boilers and generators, building materials and other supplies. VAT exemption also applies on local purchases of goods and services supplied by companies in the Kenyan Customs territory or domestic market. Motor vehicles that do not remain within the zone are not eligible for tax exemption;
- Perpetual exemption from payment of stamp duty on legal instruments;
- A 100% investment deduction on new investments in EPZ buildings and machinery, applicable over 20 years.

Major requirements for EPZ enterprises:

- Export orientation – more than 80% of sales should be made to countries outside EAC partner states;
- Local sales of up to 20% can be made subject to Cabinet secretary approval and payment of all taxes;
- Only new investments (not conversion of going concerns) in Kenya are allowed in the zones;
- EPZ location should be the primary place of business (not shell companies);
- A 100% foreign shareholding is allowed;
- There are more than 40 gazetted EPZs in Nairobi, Voi, Athi River, Kerio Valley, Mombasa and Kilifi at various stages of development by both private and public zone developers and operators. Visit <https://epzakenya.com/> for in-depth information on EPZs in Kenya.

2) Special economic zones (SEZs)

A special economic zone is a designated geographical area of high economic importance to a country, with liberal economic laws and highly developed infrastructure. These zones are provided for in the Special Economic Zones (SEZ) Act of 2015 in order to foster investments in the country. SEZs differ from EPZs, as they include an option to sell their products locally or export without restrictions. The activities that can be carried out within the SEZ are wider than in an EPZ, where the investor will be restricted to manufacturing, zone developer and export-oriented services. Activities to be carried out in a special economic zone include:

- Industrial parks;
- Free trade zones;
- Free ports;
- ICT parks;
- Science and technology parks;
- Agricultural zones;
- Tourist and recreational zones;
- Business service parks;
- Livestock zones.

SEZs are located in Mombasa (3,000km²), Lamu (700km²) and Kisumu (700km²). As per the SEZ and EPZ Acts, government is the owner of the land and investors apply to develop it for the business purpose that is approved.

Land in Kenya is expensive and the value continues to escalate each year. For instance, private land could cost between \$100 thousand and \$8 million per acre in major towns. Private land development is also subject to public participation process by the National Environmental Management Authority (NEMA), which can be lengthy and challenging. It is important to note that, for FDI in the pharma sector, SEZs are a favourable choice, as the associated costs are uniform irrespective of the location. It is also good for greenfield projects, which allow for incorporation of latest technologies and designs. For investors, greenfield in SEZ offers opportunity for both exports and local consumption.

1.6. RISK ANALYSIS OF INVESTING IN KENYA

Kenya has one of the largest and most diversified economies in Sub-Saharan Africa and enjoys many opportunities for trade facilitated by its strategic position in the region. The implementation of a robust development agenda that encompasses business-related reforms is making the country increasingly attractive for investment. Kenya came in 4th position among African countries in the Ease of Doing Business report 2019 by World Bank Group, and in the 61st position globally compared to the 2018 report when it was ranked 80th, and 113th in 2016. Kenya is also a regional giant in information and communications technology (ICT) and was ranked as 2nd leading innovation hub in Sub-Saharan Africa by the World Intellectual Property Organization (GII) 2019 report. Agriculture and tourism are the major economic drivers.

Nevertheless, the country encounters numerous risks that could deter both local and foreign investments. These include political, economic and financial risks described below.

POLITICAL RISKS

In Kenya, periodic general elections are held after every five years and election-related risk may increase in the run-up to presidential polls, although the electoral reform law, supported by all political parties, offers great prospects for a non-violent outcome. Elections in the last 10 years have not had significant effect on economic growth performance. The reconciliation agreement between the government and the opposition in 2018 aims to promote inclusivity in the government and avoid a “winner takes it all” situation, which usually results in disputes and violence. Kenya’s commitment to strengthening democracy as well as the devolved government have helped to ease political tensions. Following the much-acclaimed “handshake”, the country has experienced peace and cessation of street demonstrations, which hitherto were unpredictable.

The Kenyan Constitution 2010 protects private property and provides safeguards against expropriation of such property without compensation. Kenya is also a signatory to the Multilateral Investment Guarantee Agency (MIGA), an agency of the World Bank offering political and economic risk insurance, and a member of the International Centre for the Settlement of Investment Disputes (ICSID).

In case of commercial disputes, Kenya has a Commercial Court under the Kenyan judiciary. Peace and stability are essential for investors. The country's military involvement in Somalia, which has had major insecurity and instability, has resulted in Kenya being a target of terrorism. The reports on terrorist attacks and travel advisories, from markets such as United States and Europe, have had an adverse effect on the tourism sector. However, such travel advisories have decreased significantly. In fact, Kenya has hosted many international meetings in recent times, including the African Caribbean and Pacific Summit of Heads of State and Government December 2019, the United Nation's International Conference on Population and Development (ICPD) in November 2019, and several others earlier.

Kenya is a member of the 79-member Global Coalition against ISIS in its endeavour to fight terrorism. Efforts to tackle crime in Kenya include installation of a national secure communication network and surveillance system.

Further, additional armoured vehicles have been procured and the police force equipped to respond to emerging security threats, which have significantly enhanced national security.

ECONOMIC RISKS

Kenya has one of the largest and most diversified economies in Africa. The country has had a steady economic growth. In 2014, Kenya became a lower-middle income country (LMIC) according to World Bank country classification. In 2018, GDP growth improved to 6.3% from 4.9% in 2017. This growth is expected to accelerate further in 2020. Government spending on the Big Four Agenda infrastructure projects has driven economic growth. Corruption in Kenyan Government institutions continues to be a major hindrance to economic development.

CORRUPTION

East African countries have repeatedly been ranked among the most corrupt by Transparency International, with Kenya ranking at position 144 out of 180 countries in the 2018 index. The current constitution represents a key milestone for the fight against corruption, by limiting interference from executive powers, strengthening legislative oversight, increasing the judiciary's independence and devolving central administration to county governments. The fight against corruption is high on

the political agenda and several reforms and laws have been enacted, including the Anti-Corruption and Economic Crime Act. Also, the Public Procurement Regulatory Authority exists to monitor public procurement to ensure procurement processes comply with the requirements of the Act.

The country also signed into law the 2016 Bribery Bill, which set strict penalties for individuals or organizations involved in corruption. Furthermore, Kenya and the other members of the EAC signed the 2016 East Africa Code of Conduct, which seeks to heighten ethical business practices in the region. The fight has been heightened with several arrests of high-ranking government officials and public awareness against corruption advocated at high government level and office of the president for zero tolerance to corruption.

FINANCIAL SYSTEM RISK

The International Monetary Fund (IMF) describes the banking system in Kenya as "stable and resilient", despite emerging vulnerabilities associated with domestic and external uncertainties. The CBK is adopting new business models such as financial technologies and innovations to spur growth and control risks. Appropriate monetary policies are instituted to ensure overall inflation is in the target set by the National Treasury.

Kenya has maintained macroeconomic stability over the years. The overall inflation averaged 4.7% in 2018 compared to 8% in 2017, supported by lower food prices. Inflation has remained within the target range of 2.5%–7.5%. Food prices may occasionally fluctuate due to drought, which affects agriculture, but inflation is projected to remain approximately 5% for the 2019/20 and 2021/22 financial years.

Interest rate cap law came into effect in 2016 with the intent to reduce the cost of borrowing, expand access to credit and increase the return on savings. However, the law has not achieved its anticipated objectives according to the International Monetary Fund (IMF) report, leading to a decline in bank credit to micro, small and medium-sized firms. This has had a negative impact on economic growth and financial inclusion and constrained foreign investment in the wholesale and retail trade sector. Kenya lifted the interest rate cap in November 2019, in a move meant to revive shrinking credit access to the private sector. The repeal of interest caps in November 2019 restored the CBK control over monetary policy.

1.7. PHARMACEUTICAL PRODUCTION IN AFRICA

Africa produces less than 2% of the medicines it consumes and imports as much as 70%–90% of its need. Even so, the value of the continent's pharmaceutical market is growing rapidly and increased to approximately \$28.56 billion in 2017 from \$5.5 billion in 2007.⁸ It is predicted that the market will be worth \$56 billion to \$70 billion by 2030. High growth in this industry is still achievable, offering opportunity for investment in this sector.

This is mainly due to the rise of major cities, a stable business climate, maturing regulatory systems and the growing African population projected to reach 1.7 billion in 2030.

Value of EAC region pharmaceutical market

The increasing non-communicable diseases (NCD) burden and continued prevalence of infectious diseases in the EAC region provides opportunities for pharmaceutical manufacturers. The value of the EAC pharmaceutical market is estimated at \$1.74 billion⁹ with a compound annual growth rate (CAGR) of 10% (2007–14). Kenya's pharmaceutical market was ~\$826 million in 2016, \$919 million in 2017¹⁰ and ~\$1 billion in 2018 according to the Pharmacy and Poisons Board (PPB) of Kenya. Kenya's pharmaceutical market is growing fast, with an estimated compound annual growth rate of 7.6%–12% in the next five years.⁵ The value of imported medicines in Kenya is estimated at ~\$650 million (70%) annually, with local manufacturers covering the remainder (30%) of the domestic market. The Kenyan pharmaceutical industry is strategic in the country's development agenda as a means to boost manufacturing and affordable healthcare.

EXPORTS FROM KENYA TO THE REGION

Kenya is the biggest exporter of finished pharmaceutical products in the EAC region. The EAC export values show a rise from \$46.7 million in 2006 to \$84.7 million in 2015.

1.8. KENYA – AN OPPORTUNITY FOR PHARMA INVESTORS

Kenya is the fastest-growing pharmaceutical market in Africa.⁵ A Business Monitor report on pharmaceutical manufacturing reports Kenya as a potential base for export across East Africa.¹¹ The pharmaceutical industry has evolved from the pre-independence period (before 1963) when manufacturers were mainly foreign direct investments (FDI). The government developed policies that enabled growth of the local pharmaceutical industry after independence. Currently, the industry consists of 35 manufacturers, the majority of which are in Nairobi and its outskirts. Five factories are based in the SEZ/EPZ zones while the rest are on private land (local ownership).

The pharmaceutical industry has embarked on technology and facility upgrading to ensure adherence to Good Manufacturing Practices (GMP) standards, with some firms pursuing international certification. Kenya's production has continued to grow consistently and increased approximately fivefold in 2007–13.¹¹ In 2019, the annual sales for each of the eight big manufacturers was \$10 million to \$20 million.

The pharmaceutical industry in Kenya has great potential to grow, because there is political will to support the sector, as demonstrated by the presidential Big Four Agenda, which includes manufacturing and universal health coverage, among other sectors. Pharmaceuticals are also mentioned as one of the 18 strategic sectors in the National Industrialization Policy 2011–15 (Ministry of Industrialization, 2010). In addition, policies, laws and guidelines are being reviewed and aligned to support local pharmaceutical production in terms of access to quality medicines.

Four new greenfield FDI companies have been licensed to manufacture in the last three years, namely Square Pharmaceuticals Ltd. from the People's Republic of Bangladesh, Dinlas Pharma Ltd from India, Tassa from the United Kingdom and more in the pipeline. In January 2018, a new pharmaceutical factory valued at ~KSh 7.5 billion investment (\$73 million) broke ground in the export processing zone at Athi River. Also, a German multinational parenteral products company bought into one of the small-medium IV fluids manufacturers in Kenya. Universal Corporation Ltd, a WHO-prequalified company, entered a joint venture partnership in 2016 with Strides Pharma, India.

Numerous investment opportunities exist in the pharmaceutical manufacturing industry in Kenya. These include investing in existing facilities (mergers, acquisitions and brownfield investments) and construction of new production facilities from the ground up (greenfield investments).

KENYA'S PHARMACEUTICAL MANUFACTURING INDUSTRY AT A GLANCE

Pharmaceutical market	\$1 billion (2018)
Licensed manufacturers	35
Top manufacturers	Beta Healthcare Ltd., Cosmos Limited, Dawa Limited, Elys Chemical Industries Ltd., GSK, Laboratory and Allied Ltd, Regal Pharmaceuticals Ltd., Universal Corporation Ltd.
WHO pre-qualification (PQ) manufacturers	2
Firms in EPZ/SEZ	5
Type of manufacturing	Produce mainly non-sterile products using imported raw materials. Main products: Tablets, capsules, creams, ointments and liquids.
Products	Antibiotics, antiprotozoal agents, analgesics, antihistamines, dermatologicals, antiasthmatics, antimycotics and antacids – 30% of Kenya's demand produced.
Capacity usage	40%–50% (2 shifts)
Export destination	Kenya is the largest producer of medicines in the COMESA region.
	Exports to Tanzania, Uganda, the Democratic Republic of the Congo, Rwanda, Burundi, the Union of the Comoros, Ethiopia, the Republic of Malawi, the Republic of Zambia and the Republic of Mozambique, among other destinations.
Compound annual growth rate (CAGR)	7.6%–12% in next five years
	Kenya is the fastest-growing pharmaceutical market in Africa.
No. of employees	Approximately 4,000; with adequate skills for current product portfolio.
Drug regulatory authority	Pharmacy and Poisons Board of Kenya
Legal requirements for starting a business	Business name or company registration, single business permit Licence to manufacture and sell pharmaceutical products
Legislations that impart pharmaceutical industry	Pharmacy and Poisons Act, Cap 244, Anti-Counterfeit Act, Patent Registration Act, Cap 508, The Factories and Other Places of Work Act, Cap 514, Public Health Act, Cap 242, Food and Drugs and Chemical Substances Act, Cap 254, Environmental Management and Co-ordination Act, and Labour Act, Cap 226.

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MODULE 2: KEY PLAYERS IN THE KENYAN PHARMACEUTICAL SECTOR

2.1. KENYAN PHARMACEUTICAL SECTOR

The pharmaceutical sector in Kenya consists of manufacturers, distributors, wholesalers, retailers and other stakeholders, including national regulators and government ministries. Kenya has the largest hub of pharmaceutical facilities in East Africa, with more than 60% of manufacturers in the region.¹ Enabling policies exist and manufacturing is regulated to ensure product quality.

a) Policies and legislation supporting pharmaceutical manufacturing

The Kenya Health Policy 2014–2030² is anchored in the Kenya Constitution 2010, Vision 2030, which requires the country to provide the highest attainable healthcare, right to health and consumer right to quality products, including access to essential medicines.³ This is clearly stated in the Kenya National Pharmaceutical Policy,⁴ Sessional Paper Number 4 of July 2012, and the Kenya Pharmaceutical Strategic Development Strategy of 2012.⁵ These documents describe how access and availability of safe, effective and quality essential medicines is to be achieved. These initiatives emphasize the Kenyan Government's commitment to supporting local pharmaceutical production and epitomizes the “Buy Kenya Build Kenya” marketing slogan for domestic industrialization and preferential procurement initiatives. The pharmaceutical policy puts attention and priority on self-sufficiency and local production of essential medicines. It calls on the government to create an enabling environment to encourage investment in the sector, transfer technology and facilitate attainment of international standards. The investor is required to adhere to the specified GMP standard. Kenya's Industrial Property Act meets the terms of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and allows innovation and patent protection.

b) Regulation of pharmaceutical sector

The Pharmacy and Poisons Board (PPB) regulates pharmaceutical manufacturing in Kenya by implementation of suitable regulatory measures. The PPB performs regular inspections of local and foreign pharmaceutical manufacturers to ensure compliance with GMP. The PPB also ensures compliance with Good Distribution Practices (GDP) and authorizes the marketing of all medicines

through a product registration process. The PPB also carries out post-registration monitoring to ensure that all medicines in Kenya conform to the recommended standard of quality.

c) Quality status of pharmaceutical industry

The launch of the Kenya GMP Roadmap in 2014 with the technical support of UNIDO has been instrumental in facility upgrades, quality improvements and new investments in the sector. The EAC Regional Pharmaceutical Plan of Action also supports the development of the sector (2017–2027).¹ At present, two local pharmaceutical production facilities and two quality control laboratories have attained WHO prequalification status,⁶ which is proof of growth of the local pharmaceutical industry and also offers opportunities for investment in this sector.

The level of GMP compliance varies in the industry based on the manufacturer's vision and target market.⁷ All facilities are licensed by the Pharmacy and Poisons Board (PPB), which is the local medicines regulatory authority (MRA), and also seek international and/or regional GMP certification via the EAC harmonization project.⁸ The project aims to achieve a harmonized medicines registration process in its member countries (Uganda, Kenya, Tanzania, Rwanda and Burundi) based on common documents, processes and information. One manufacturer (Universal Corporation Limited, UCL) and Questa, a firm that is involved in packaging of imported bulk medicines, have achieved international (WHO PQ) certification. UCL entered a joint venture partnership in 2016 with Strides Pharma, India, as a gateway to the EAC region.

d) Pharmaceutical manufacturers' affiliation

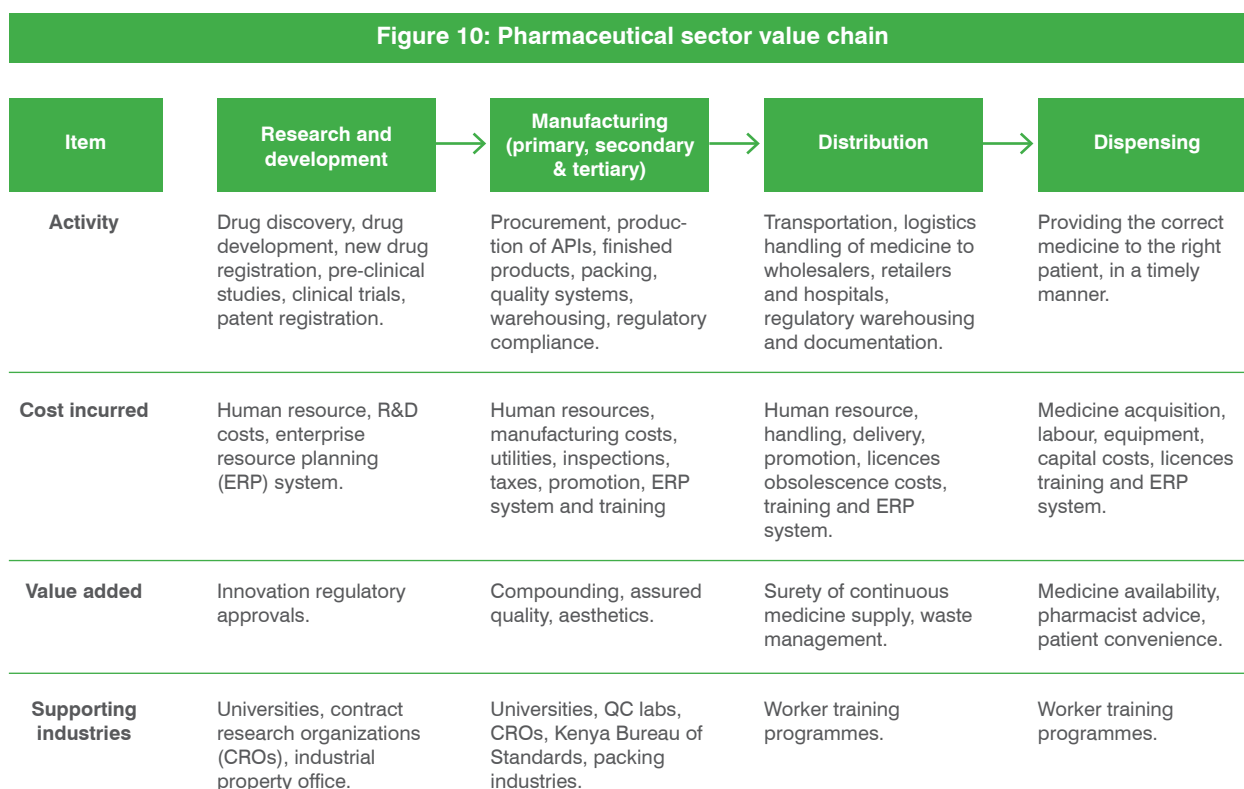
The Federation of Kenya Pharmaceutical Manufacturers (FKPM) is the umbrella body that represents the manufacturer's interests on policies, trade and product quality at relevant fora within the country. The FKPM is a member of the Federation of East African Pharmaceutical Manufacturers (FEAPM), which is affiliated with the Federation of African Pharmaceutical Manufacturers Associations (FAPMA). The FAPMA is the continental umbrella advocacy body for pharmaceutical production in Africa committed to establishment of a sustainable and self-sufficient source of quality essential medicines.⁹

2.2. PHARMACEUTICAL SECTOR VALUE CHAIN STRUCTURE

Typical pharmaceutical manufacturing (Figure 10) encompasses interrelated activities that enhance a product for the market and produce value at each stage of activity.¹⁰ Value creation at each stage, starting from drug discovery to retail distribution, is added in a typical pharmaceutical value chain.¹¹

Value chain analysis provides vital data on most valuable activities, which can be optimized for competitive advantage. Table 11 shows the Levels of pharmaceutical production in Kenya. The pharmaceutical value chain starts from importation of finished products for distribution to re-packing of products, production of finished products and minimal production of inputs. There is an increasing level of

complexity and value addition as well as regulatory requirements at each subsequent level. There is very limited research and development (R&D) and post-training in industrial skills in the pharmaceutical industry in Kenya. This is an area that investors could consider in partnership with government. The contributory factors include shortage of adequate and appropriately trained scientists, lack of investment capital, poor access to infrastructure, absence of enabling technology platforms and suboptimal policies that support R&D. Coherence of policies is necessary for effective implementation of programmes aimed at improving pharmaceutical production to meet public health needs.¹²



Source: Murray Aitken (2016). Pharmaceuticals Policy & Law.

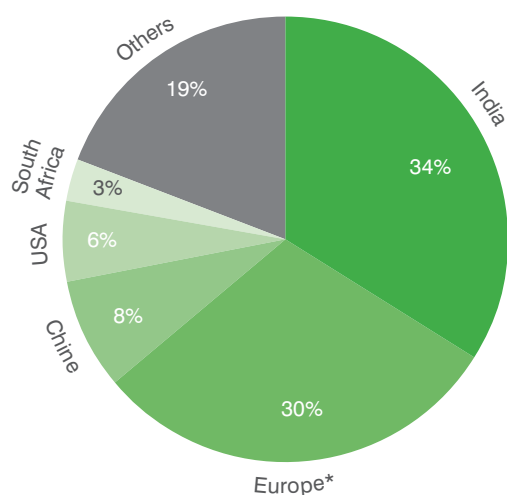
Table 11: Levels of pharmaceutical production in Kenya

Level	Activity	Number of firms
1	Importation of finished products/marketing and sales (majority)	≈1 000 (wholesale)
2	Tertiary manufacturing – focus on re-packaging and labelling	1
3	Secondary manufacturing – formulation and production of finished products	35
4	Primary manufacturing – production of active pharmaceutical ingredients (API)	1
5	Research and development – nascent stage	5 (basic research)

IMPORTATION OF FINISHED PRODUCTS

Limited pharmaceutical innovation and inability of the local pharmaceutical industry to significantly produce low-cost quality generic products has allowed foreign companies to dominate the pharmaceutical market. Kenya imports mainly from Europe and Asia (India and China). Most of the original/brand medicines are from Europe and are imported through local agents. Few have scientific offices for promotion of products. Most generic products are imported from India and China. Figure 11 shows the country of origin of imported pharmaceutical products in Kenya in 2018.

Figure 11: Country of origin of imported pharmaceutical products in Kenya (2018)



* Switzerland, UK, Germany, Belgium, France

Source: PPB data, 2018.

The value of imported finished pharmaceutical products in Kenya is estimated to be 70% of the total market. Up to 100% of specific products such as vaccines are imported.¹³ The PPB performs post-registration monitoring of medicines to ensure compliance with Good Distribution Practices and to reduce entry of counterfeits into the supply chain.

RESEARCH AND DEVELOPMENT

Drug discovery and development of conventional medicine by the Kenyan pharmaceutical industry is yet to develop. A few manufactures have operative R&D departments focusing mostly on making generic forms of innovator products. Nonetheless, partnerships with academia and research institutes could unlock this dilemma. Kenya has seven schools of pharmacy and a well-established research institute, the Kenya Medical Research Institute (KEMRI), which has extensive global research linkages with leading health research organizations. In addition, R&D in herbal/complementary medicine is feasible, as KEMRI hosts the Centre for Traditional Medicine and Drug Research (CTMDR), which is authorized to carry out research to justify the use of traditional medicine in Kenya. Furthermore, all the schools of pharmacy have a department that deals with the study of medicinal plants. Since the use of traditional medicines with proved efficacy is common in Kenya, advancing research in alternative medicines and creation of applicable legal framework is a worthwhile venture.¹⁴⁻¹⁷

PHARMACEUTICAL INPUTS

More than 90% of active pharmaceutical ingredients (APIs) and excipients used in pharmaceutical production are imported, mostly from India and China.¹³ A few excipients are manufactured locally and these include maize starch, refined sugar and rectified spirit. Crude artemisinin produced by East African Botanical Extracts EPZ Limited and exported to India for its purification is the only API currently produced in Kenya. Small manufacturers purchase most of the raw material from local traders.

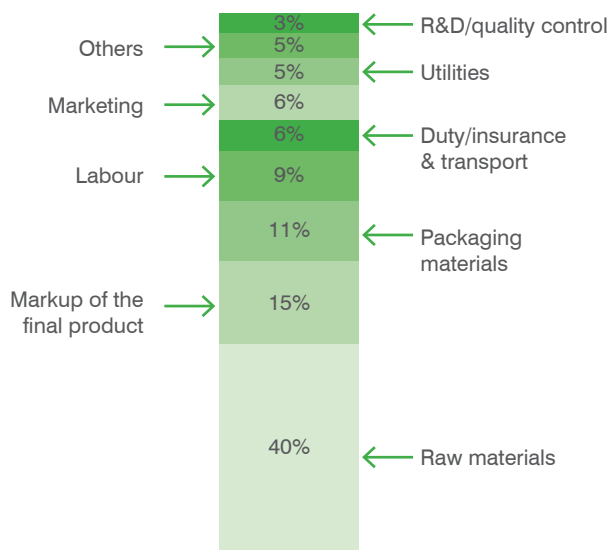
Nearly 60% of packaging materials are imported (Table 12). Production equipment and utilities are also imported. Raw materials and packaging materials contribute approximately 51% of the wholesale price of the finished product.^{13, 18}

Table 12: Packaging materials that are imported

Packaging Material	% Imported
Glass bottles	80
Plastic bottle/containers	45
Labels/unit boxes	70
Blister foil/PVC	100
Outer cartons	0

Source: Vugigi et al. (2017).

Figure 12: Cost distribution (%) of a final pharmaceutical product



Source: Vugigi et al. 2017.

PHARMACEUTICAL MANUFACTURING

The local production of pharmaceutical products was established in Kenya in the 1940s.¹⁹ Pharmaceutical manufacturing firms are engaged in secondary and tertiary production of generic medicines for human and veterinary use. All medicines are subjected to pre-marketing evaluation and marketing authorization by the PPB before commercial production. Pharmaceutical inputs are compounded to the finished product following established operating procedures in compliance with regulatory requirements (Good Manufacturing Practices). The finished products are then packed and labelled appropriately for sale and distribution.

A range of medicines are produced, mainly non-sterile forms such as tablets, capsules, liquids and skin preparations. Beta lactam and non-beta lactam products are manufactured. Six firms manufacture beta lactam products. Less than 40% of Kenya's listed essential medicines (EM) are manufactured locally.¹³ Common and simple formulations are produced. Products that require complex manufacturing processes and adherence to strict controls are not produced.

A large percentage of products that are manufactured are for management of communicable diseases. A few companies are developing medicines for use in the treatment of lifestyle diseases such as anti-diabetic and cardiovascular products in response to the increasing burden of

non-communicable diseases. An estimated 66% of disease conditions in Kenya are managed by locally produced medicines. The leading categories produced include antibiotics, antiprotozoal agents, analgesics, antihistamines, dermatologicals, antiasthmatics, antimycotics and antacids. A few facilities make sterile products. There are two large-volume and one small-volume parenteral manufacturers. The local industry produces limited variety and quantities of the cardiovascular drugs, anti-diabetics and parenteral products. Antidotes, diagnostics, oxytocics, chemotherapeutics and peritoneal dialysis solutions are not produced, and these production lines provide opportunity for investment in terms of product range and new technologies.

Production capacity is underused. In 2019, the average capacity usage was 43% for non-beta lactam products (tablets, 48%, capsules, 28% and liquids, 52%). Furthermore, most local firms are disqualified from donor-funded government procurement since participation is only open to WHO-prequalified facilities. However, investors could take advantage of the existing idle production capacity through partnerships (e.g. joint ventures) and expand product range, among other interventions, with the aim of introducing competitive local products in the market.



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DISTRIBUTION (WHOLESALE/RETAIL) TO CONSUMERS

The finished pharmaceutical products supply chain in Kenya is illustrated in Figure 13. The distribution system of these products is classified into public (government), non-governmental organizations (NGOs) and private channels (Figure 14).⁷ The Kenya Medical Supplies Authority (KEMSA) is the main government procurer, with nearly 30% of all prescription drugs purchases in the Kenyan market. Public facilities source their medicines from KEMSA or through the local district hospitals. KEMSA has two warehouses in Nairobi, eight depots across the country and a national distribution coverage serving more than 4,000 public sector facilities. The Mission for Essential Drugs and Supplies (MEDS) is a large non-governmental organization that procures medicines for faith-based organizations.⁷ MEDS supplies medicines to more than 1,820 health facilities.²⁰ Kenyatta National Hospital, the largest public and referral hospital in Kenya, is also a major procurer. Non-profit facilities purchase their medicines from MEDS, wholesalers or the private sector.

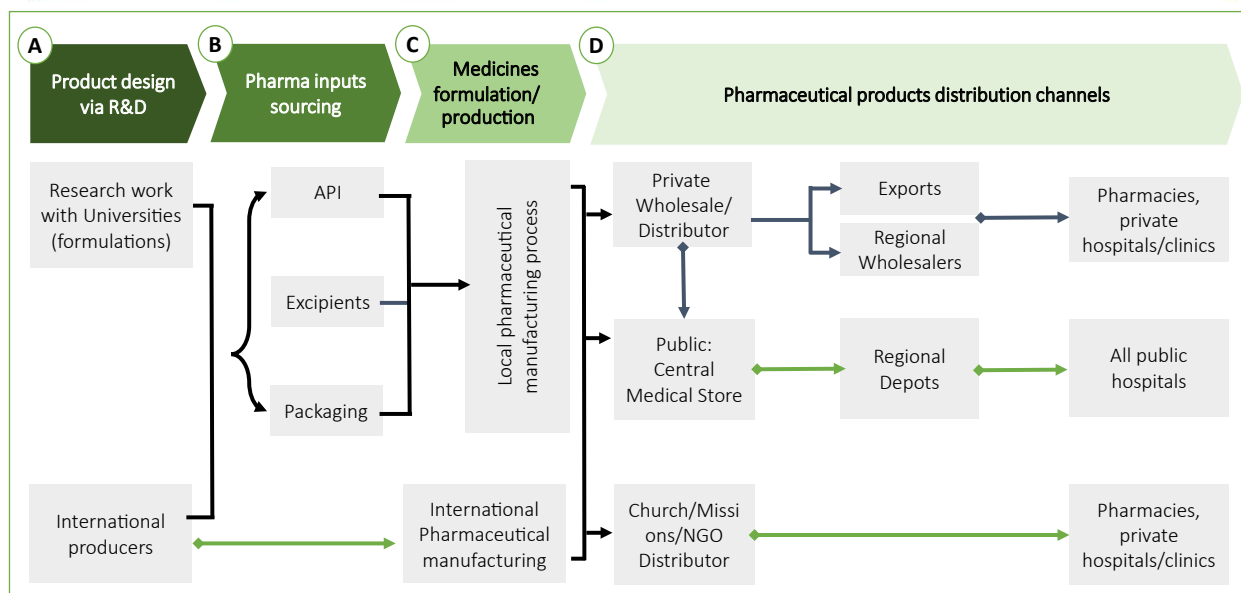
The private pharmaceutical distribution system in Kenya has clear structures and is well established and organized. However, it is fragmented, comprising wholesale distributors handling both imports and locally manufactured goods. There are more than 30 large distributors in Kenya supplying a much larger number of wholesalers. The distributors and wholesalers are registered by the PPB. The wholesalers sell to multiple sub-wholesalers, who then sell to private retail pharmacies, hospitals and health centres. It is estimated that there are more than 6,000 pharmacies in Kenya.²⁰ Mark-ups are added at each level in the supply chain, which, in most cases, results in high prices at pharmacy retailers. The pharmaceutical market in Kenya is dominated by generic products (63%). Anti-infectives, anti-diabetics and cardiovascular drugs constitute the largest and fastest-growing prescription market segments.²¹



2.3. PLAYERS IN THE PHARMACEUTICAL SECTOR VALUE CHAIN

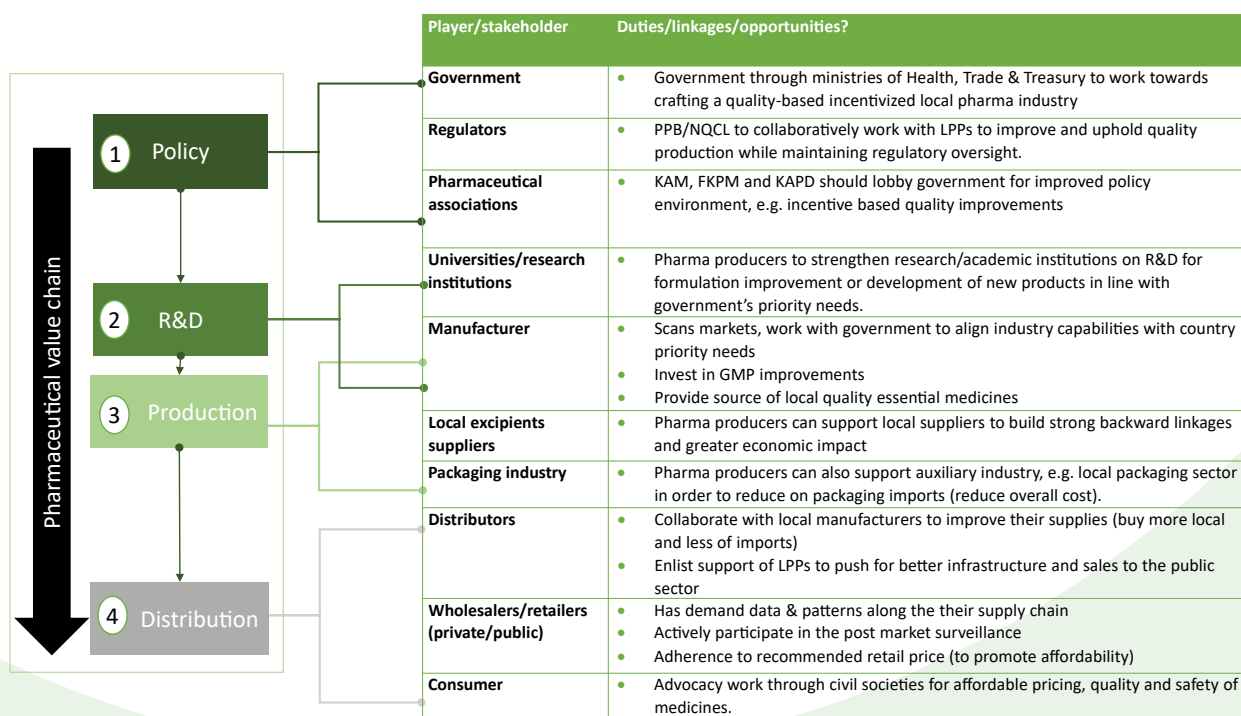
There are several players in the pharmaceutical value chain. It encompasses manufacturers, distributors, policy actors, regulators and consumers, among others. Please see the summary of the players and how they are linked in Figure 14.

Figure 13: Kenya finished pharmaceutical products supply chain



Source: Creating markets in Kenya report, World Bank (2019) and Consultant's knowledge of the sector.

Figure 14: Pharma sector value chain players



2.4. SWOT ANALYSIS FOR INVESTING IN KENYA'S PHARMACEUTICAL SECTOR

STRENGTHS

- *Policy and regulation:* There are existing policies supporting local production (including Kenya National Pharmaceutical Policy (KNPP), Kenya Pharmaceutical Sector Development Strategy (KPSDS), Kenya health policy, industrialization policy, and the Big Four Agenda for development), enhancing top government and political goodwill.
- *Technology:* Kenya has the technology to make solid, semi-solid and liquid formulations. At least two firms have voluntary licensing to manufacture antiretrovirals.
- *Markets:* Fast-growing and well-established export market across East, West, Central, and North and Southern Africa, except in South Africa. Kenya's medicine export to the EAC and COMESA is high at more than 50%.
- *Quality (GMP):* Reasonable quality standards with a mix of WHO prequalification (PQ) and WHO GMP facilities and low level of counterfeits reported.
- *Continuous upgrades* for improved quality infrastructure and systems.
- *Growing auxiliary industry:* Contribution to industry growth (plastic and packaging, etc.).
- *Infrastructure:* Government investments in infrastructure (SGR railway, airport and ports, etc.).
- *Taxation:* No tax on medicines and no duty on importation of medicines.
- *Stability:* Steady economic and political stability.
- *Health budget:* Increasing national and county governments (KEMSA & MEDS buying more local) have increased quantities and additional treatment regimens.
- *Regional harmonization of GMP standards and medicines registration procedures:* Market authorization boosts access to markets by market expansion since the EAC regional economic bloc is deemed local by the EAC marketing protocol.

WEAKNESSES

- Imports more than 90% active pharmaceutical ingredients and machinery.
- Inadequate technology transfers in advanced formulations, e.g. vaccines and complex formulations.
- Insufficient innovations, new formulations and new products from R&D.
- Insufficient implementation of policies, e.g. generic prescribing.
- Uneven playing field in the distribution chain of products from facilities with low-level GMP standard.
- Inadequate enforcement of laws due to weak sanctions.
- Poor access to affordable investment funds.
- Lack of supportive infrastructure, e.g. bio-equivalent study centre.

OPPORTUNITIES

- Capacity building to improve trained and skilled workforce in pharma manufacture and know-how.
- Investment in sterile product manufacturing facilities.
- Market penetration: Large public and private market in the EAC, COMESA and the rest of Africa can be explored.
- Technology transfers, new investments and innovative products.
- Formulation of pro-local pharmaceutical production incentives.
- Pro-local pharmaceutical producers (LPP) policies, regulations and guidelines and strengthening of good corporate image.
- Establishment of skills development institutions (public or private).

THREATS

- Underdevelopment of local capacity in donor-driven supplies due to local pharmaceutical producers being locked out by stringent tender requirements (e.g. WHO PQ).
- Dumping of medicines in event of outages of essential medicines.
- Inadequate rigid regulatory controls may lead to poor-quality products in the market.

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MODULE 3: OPPORTUNITIES IN PHARMACEUTICAL MANUFACTURING IN KENYA

3.1. INVESTMENT AREAS SNAPSHOT

The pharmaceutical industry in Kenya offers excellent opportunities for investment across the whole pharmaceutical value chain, targeting the domestic market, COMESA region and the rest of Africa. There is ample scope for investment considering that the majority of inputs and finished products are not manufactured locally and that production capacity is underused. Potential investment areas along the value chain in this sector

are in R&D, in partnership with research institutions such as the Kenya Medical Research Institute (KEMRI), bulk production of pharmaceutical inputs and production of finished products. A significant number of manufacturers adhere to stringent GMP standards, which is conducive to investors who wish to partner with GMP-compliant companies. See table below for potential investment opportunities.

3.2. POTENTIAL INVESTMENT AREAS ACROSS THE PHARMACEUTICAL VALUE CHAIN

Value chain	Investment type/description	Existing limitation	What is needed
R&D	Innovative R&D R&D partnerships Infrastructure	R&D is beyond academic. Translation of R&D work to innovation and novelty remains a challenge. Inadequate linkages. Poor infrastructure.	Innovation of new products and new treatment regimens from existing products. Create research linkages. Set up contract research organizations (CROs), including bioequivalence (BE).
Manufacturing	Pharmaceutical inputs	Nearly all raw materials are imported. Kenya has a few non-pharmaceutical grade excipients.	Purification of existing excipients to pharmaceutical grade.
	Conventional medicines	Local pharma produces approximately 25% of essential medicines.	New product formulations. New high-value products based on emerging disease trends.
		Manufacturing process technology is mostly imported.	Training and incubation centres, cottage industries, production of product master batch for upscaling and technology transfer.
	Complementary/alternative medicines	Non-scientific knowledge on the use of alternative medicines is widespread.	Isolation and production of bulk. Formulation of stable modern packaged traditional medicines.
	Auxiliary products/borderline items, including those used in industry to enhance quality	Standardization of toiletry industry and related industries not adequate.	Production of hygiene and sanitation products, protective garments, upgrading of toiletry industry, special containers for medicines and dispensing, etc.
	Production and quality control equipment and machinery	Expensive machinery. Aspects of required machine service not available locally.	Design and installation firms. Metrology/standardization/calibration firms. Development of local input.
Distribution	Warehouse and logistics	Public warehousing and logistics.	Private sector warehousing, preferably GMP level.
Dispensing	Medicine delivery	Few home deliveries available.	One-stop shop and deliveries to homes, e.g. chronic medications.

3.3. INVESTMENT OPPORTUNITIES IN THE PHARMA SECTOR

R&D PARTNERSHIPS

Kenya's Vision 2030 directs the manufacturing sector to increase the generation and usage of R&D results. The Ministry of Industrialization has in place an R&D policy to ensure commercialized research through linkages with academia, research institutions, the manufacturing sector and investors. Kenya also has numerous research institutions, for example, Kenya Medical Research Institute (KEMRI), an establishment that has successfully developed biomedical products such as Hepcell and is keen to develop and commercialize diagnostic kits through partnerships. Priority research areas for KEMRI include development of biosimilar products that are in demand in the region. The existing infrastructure provides viable investment opportunities through R&D partnerships. Furthermore, Kenya's Industrial Property Act allows innovation and patent protection and meets the terms of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement.

PRODUCTION OF VACCINES

The WHO-recommended vaccines for Kenya are: hepatitis A, hepatitis B, typhoid, cholera, yellow fever, rabies, meningitis, polio, measles, mumps and rubella (MMR), TDAP (tetanus, diphtheria and pertussis), chickenpox, shingles, pneumonia and influenza. Immunization coverage in Kenya was 82% in 2018 and the National Policy guidelines (2014) target 100% coverage. Vaccine production provides a glaring investment opportunity given that, presently, all vaccines in Kenya are imported. Furthermore, Kenya's industrialization agenda and the pharmaceutical policy promote local production. Discussions are underway between a Kenyan firm and Merck for a joint venture in vaccine production.

PRODUCTION OF PHARMACEUTICAL INPUTS

Kenya produces a few non-pharma grade raw materials such as sugar, common salt (sodium chloride) and ethanol. These can be processed to pharmaceutical grade for use in the pharma industry, targeting the domestic and entire COMESA region. Large quantities of sugar are used in the production of liquid syrups and dry syrups. Sodium chloride is used to manufacture oral rehydration salts (ORS), which is used to manage diarrhoea. In Kenya, diarrhoeal disease is the second leading cause of death among children under five years. However, less than 20% coverage of ORS has been achieved.

The government has launched a national plan to increase the coverage to avert the mortality. Another possibility is the production of hecogenin, a steroid precursor extracted from sisal plant grown large scale in Kenya.

PRODUCTION OF STERILE PRODUCTS

Approximately 40% of the medicines on the essential medicines list are sterile products. There are only three manufacturers of sterile medicines in Kenya, producing approximately 10% of the required sterile products. As such, there is room for more investment in sterile products production. Kenya's Vision 2030 and the pharmaceutical policy promote local production. Also, Kenya has designated special economic zones and export processing zones with requisite infrastructure to provide incentives to potential investors.

PRODUCTION OF CARDIAC AND DIABETIC PRODUCTS

More than half of in-patient admissions in Kenyan hospitals are due to non-communicable diseases, mainly cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. These diseases are among the top killers in Kenya. Kenya is cognizant of the increasing prevalence of non-communicable/lifestyle diseases in the country and a strategy for control is under implementation. Cardiovascular is Kenya's most dominant and fastest-growing prescription market segment. The local industry does not produce most of the cardiovascular and anti-diabetics drugs; hence, an opportunity for investment.

PRODUCTION OF BETA-LACTAM PRODUCTS

Communicable diseases remain the leading cause of death in Kenya, even though there is a substantial decline; hence, demand for anti-infectives continues to be high. β -lactam antibiotics are the most commonly prescribed antibiotics and form approximately 50% of anti-infectives that are sold in Kenya. Few manufacturers produce β -lactams due to their stringent GMP requirements. Also, only the penicillin class of the four common β -lactam derivatives is manufactured, thus opportunity exists for production of the whole range of beta-lactam products in Kenya.

PRODUCTION OF ANTI-CANCER AGENTS

According to the Global Cancer Observatory (GLOBOCAN) (2018), an estimated 331,177 new cancer cases were reported in Eastern Africa in 2018. Cancer was ranked 3rd as a cause of death in Kenya in 2017, an indication that there is demand for anti-cancer medicine in the country. No anti-cancer medicine is manufactured in Kenya. The National Cancer Control Strategy for 2017–22 is under implementation, and this reflects the government's commitment to reducing the incidence of cancer and improving the quality of life of those who develop the disease.

HERBAL/ALTERNATIVE MEDICINES

Approximately two-thirds of Kenyans seek alternative treatment for various ailments. Kenya has diverse flora and abundant basic knowledge of medicinal herbs. A pharmacopoeia on herbal medicine exists in Kenya. KEMRI hosts the Centre for Traditional Medicine assigned by the government to carry out research to rationalize traditional medicine. Also, there are several Kenyan departments that conduct research on alternative medicines. Standardization and commercial processing of herbal medicines can be exploited. The Health Act 2017 specifies the formation of a body to regulate the practice of alternative medicine in Kenya.

HOSPITAL EQUIPMENT, MEDICAL DEVICES, DIAGNOSTICS AND DRESSINGS

The region imports all equipment, medical devices, diagnostics and dressings that are used in hospitals. Some of these can be made in Kenya. For example, devices that do not require stringent regulatory controls such as disposable surgical gloves, latex gloves, syringes and medical gauze.

DEVELOPMENT OF LOGISTICS AND WAREHOUSING

Currently, manufacturers operate their own warehouses. However, this is not sufficient and points to a need for warehousing as a service. For instance, GMP-certified warehouses could serve as inventory holding for active pharmaceutical ingredients and other excipients that may have longer lead times.

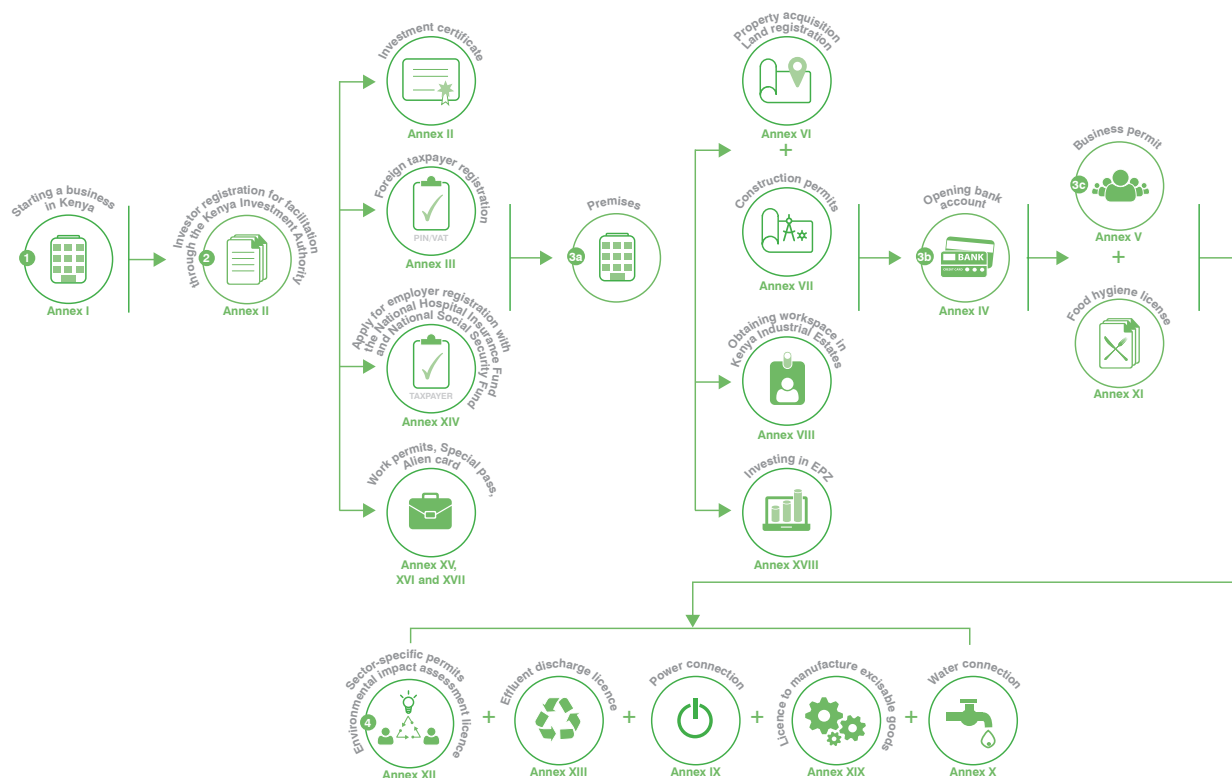
JOINT VENTURES

Approximately 10 manufacturers have upgraded their facilities to attain high GMP standards. Two companies have achieved WHO certification and three are Pharmaceutical Inspection Co-operation Scheme (PIC/S) certified. The industry has an estimated 50% underused production capacity. Most companies are based in Nairobi (see manufacturing sector overview in Module 1). Kenya has quality facilities with ample production capacity, which are suitable for joint venture collaborations. This is illustrated by the Universal Corporation Ltd/Strides merger in 2016 quoted at ~\$14 million.



MODULE 4: INVESTING IN THE PHARMACEUTICAL MANUFACTURING SECTOR

Figure 15: Steps required to start a business in Kenya



Source: Partnership for Investment and Growth in Africa (PIGA). Investor Guide for Kenya: Agroprocessing and light manufacturing sectors (2018).

4.1. STARTING A BUSINESS IN KENYA

Kenya has made great strides in the ease of doing business. The World Bank Report 2018 posits that Kenya improved by 2.67% in registration of businesses. This was mainly attributable to the automation of the business registration process through the [eCitizen portal](#).

The main forms of business in Kenya include:

- 1) Companies
- 2) Limited liability partnerships
- 3) Sole proprietorships and partnerships.

The main vehicles used by investors are limited liability companies, which can be incorporated either as private companies or as public companies. Companies, whether private or public, are preferred, because they are legal entities different from the shareholders

that can be sued in their own names. Taxation is also made at the entity level, unlike partnerships or sole proprietorships, where taxation is made at the individual level. The resignation of a shareholder also does not affect the running of the company.

A private company restricts its members' rights to transfer shares and prohibits invitation of the public to subscribe for shares or a debenture of the company. Its membership is also limited to 50 members. A public company, on the other hand, allows its members (through its articles) the right to transfer their shares in the company. There is also no prohibition on invitation to the public to subscribe for shares or debenture of the company.

The limited liability can be either a local company (Kenyan) or a foreign company. A foreign company is a company that has been incorporated outside Kenya. The Companies Act 2015 allows investors to incorporate a sole director company and register

a fully owned local company without having any Kenyan shareholders. Local companies are easier to incorporate and enjoy 30% corporate tax, while foreign companies attract 37.5% corporate tax. Through the eCitizen portal, investors can register and obtain the company certificate online. This takes 5–10 working days if all requirements are met. Registration costs of a local company are KSh 10,650, while for a foreign company it is KSh 8,650. Companies with a paid-up capital of more than KSh 5,000,000 or public companies are required to have a company secretary. The company secretary is required to have a practicing certificate issued by the Institute of Certified Secretaries of Kenya (ICS). Investors can access the list of practicing company secretaries from the Institute of Certified Secretaries of Kenya's website (<http://members.icpsk.com/index.php?q=directory&alpha>) and contact them directly for their services. *See Annex I for the procedure to start a local company and a foreign company.*

Once the company has been incorporated, the investor will be required to obtain a foreign national taxpayer registration (company PIN), apply for employer registration with the National Hospital Insurance Fund and National Social Security Fund, apply for a work permit (including special pass and/or foreign national certificate/alien card to manage time limitations) and obtain an investment certificate.

CAPITAL CONTRIBUTION

The Statement of Nominal Capital form (see Annex I) indicates the company's authorized capital. Shares can be issued at par (the nominal value of the shares) or at a premium. A company cannot decrease its capital or issue shares at a discount without the sanction of the court. The authorized capital can be increased by an ordinary resolution of members in a general meeting. A Statement of Increase of Nominal Capital has to be submitted to a Huduma centre or the Lands Office for stamping within 30 days of the date of passing of the resolution. The rate of stamp duty payable is 1% of the amount by which the capital is increased. The stamped Statement of Increase of Nominal Capital has to be filed with the Registrar of Companies.

JOINT VENTURE WITH A NATURAL PERSON OR GOVERNMENT

A joint venture (JV) is a commercial collaboration in which two or more distinct parties agree to develop a new entity and new assets by contributing equity towards a mutual goal for a fixed or indefinite duration. The profits resulting from the joint venture are then apportioned according to the value of their respective contributions.

STRUCTURE OF A JOINT VENTURE

The structure of a joint venture depends on the strategic, fiscal or commercial advantages from which the parties seek to benefit. Foreign investors are advised to incorporate a company.

Once the company has been incorporated, the parties should contract an advocate to draft them a joint venture agreement to have their interests safeguarded.

4.2. FOREIGN TAXPAYER REGISTRATION (PIN AND VAT REGISTRATION)

The Kenya Revenue Authority (KRA) issues the personal identification number (PIN) to citizens and investors to enable them to make transactions such as opening accounts with financial institutions and investment banks, importation of goods and Customs clearing and forwarding, registration of titles, stamping of documents and paying of taxes. The Kenya Revenue Authority requires foreign investors to have an investor's permit (from the Department of Immigration), a foreign national certificate or an endorsement letter. KenInvest facilitates investors in obtaining the foreign taxpayer registration through issuance of an endorsement letter. *See Annex III for the procedure to obtain a foreign taxpayer registration through the Kenya Investment Authority.*

4.3. EMPLOYER REGISTRATION WITH THE NATIONAL HOSPITAL INSURANCE FUND AND NATIONAL SOCIAL SECURITY FUND

NATIONAL SOCIAL SECURITY FUND

The National Social Security Fund (NSSF) is the statutory retirement benefits scheme and provides retirement benefits for employees in the formal and informal sectors. It registers members, receives contributions, manages funds, and processes and ultimately pays out benefits to eligible members or dependents. Employers are required to register with the fund.

NATIONAL HOSPITAL INSURANCE FUND

The National Hospital Insurance Fund (NHIF) provides limited in-patient medical insurance cover at accredited health facilities to eligible members from both the formal and informal sectors. There is a mandatory requirement for employers to register with this fund in Kenya.

4.4. WORK PERMITS

Foreign nationals require authorization from the Department of Immigration Services to be present in and work in Kenya. The Department of Immigration Services has partially automated application of work permits through the electronic Foreign Nationals Services portal (eFNS). Investors can apply and pay for the processing fees online, then submit the application to the Department of Immigration Services for processing. Under Kenya's laws, the work permits applicable to the pharma sector are as follows.

CLASS	Activities
Class F	Specific manufacturing (for the shareholders and directors of the company).
Class D	For employees. This permit will only be applicable if the companies in the industry will be employing foreign nationals who are in possession of skills or qualifications that are not available in Kenya.

4.5. SPECIAL PASS

Since work permits take time (three to four months) before they can be processed, an investor can apply for a special pass to commence operations in Kenya. A special pass is issued to foreign nationals who wish to enter Kenya or remain in Kenya for:

- 1) Applying for a permit or pass;
- 2) Temporarily conducting business, trade or profession in Kenya initially;
- 3) Possibility of reapplying for the special pass for a further three months.

The procedure for hiring foreign nationals is described in Annex XV of the Investor guide for Kenya: <http://www.invest.go.ke/publications/>

4.6. FOREIGN NATIONAL CERTIFICATE/ALIEN CARD

Since the entry permit would not allow the holder to remain in Kenya for more than three months, it is mandatory that a permit holder obtains an alien certificate, which is similar to the national identification card issued to Kenyan citizens. The card identifies the holder of a permit as an alien and bears the holder's physical address. However, an alien card does not entitle the holder to conduct business for which purpose a special pass or work permit is required.

4.7. INVESTMENT CERTIFICATE

Kenya Investment Authority issues an investment certificate to investors for free. The certificate is issued upon request by a registered investor who has a proof of investment of at least \$100,000 either through money already in a Kenyan bank or assets purchased (whether locally or imported) towards initiating the project. Before the certificate can be issued, the authority will inspect the premises to ensure that the housing use of the registered premises is consistent with the enterprise's operation activities.

A holder of an investment certificate is entitled to entry (work) permits for members of the holder's management or technical staff and fellow owners (or shareholders or partners). Kenya Investment Authority is mandated to facilitate the issuance of those permits. The holder of a certificate benefits from the initial issuance of any additional licence required for their operations except for health, security (*if the investor will be dealing with armoury, armoured vehicles or any activities that touch on security*) and environmental certificates for a maximum period of one year. Until the licences are issued by their issuing authorities and for a maximum period of 12 months after the issuance of the certificate, the licences are deemed to have been issued by virtue of the certificate, subject to the submission of appropriate applications and fees. This entitlement is only for the initial issuing of licences, after which the laws under which they are normally issued apply as usual. *See Annex II for the procedures to obtain the investment certificate.*

4.8. LAND PROCEDURES

Land in Kenya is categorized as:

- a) Public land
- b) Private land
- c) Community land.

Public land is held by county governments and national governments and administered by the National Land Commission. Community land is held by communities. Private land is held by legal persons (whether a company or an individual) either by leasehold tenure or freehold tenure.

Under the laws of Kenya, non-citizens can only hold land on a leasehold basis, and the lease should not exceed 99 years. Foreign companies can buy land in Kenya. However, the company is required to be legally registered and issued with a company personal identification number by the Kenya Revenue Authority. Any transactions on the parcel of land are required to be registered. The Ministry of Lands is responsible for registration of interests in land. See Annex VI for the procedure to buy land in Kenya.

4.9. OBTAINING A WORKPLACE IN KENYA INDUSTRIAL ESTATES

Kenya Industrial Estates Ltd provides serviced workspace through construction of industrial estates/incubators in fast-growing business centres. The parastatal has constructed sheds in various parts of the country, which it lets to budding industrialists. The investors can access flexible and affordable workspace, financial support for machinery, equipment and working capital, and shared utility services, management and technical assistance, including skills upgrading, marketing, accounting, legal, secretarial services, and internet and networking. See <http://www.kie.co.ke/index.php/cde-training/9-uncategorised> for the procedure to apply for workspace/sheds at Kenya Industrial Estates.

Note: Fees quoted may change by Notice in Kenya gazette and investors should counter check with KenInvest or the respective authority at time of application.

4.10. CONSTRUCTION PERMITS

Constructions permits are issued by the county governments. They act as permits to erect structures in certain areas and ensure that it conforms to the physical planning and building code. The county governments charge different fees for the construction permit. The investor will be required to procure the services of an architect and a structural engineer. An updated list of professionals can be found on these websites: <https://www.iekenya.org/> and <https://boraqs.or.ke/members/>. See Annex VII for the procedure to obtain a construction permit in Nairobi County and Annex XII for Pharmacy and Poisons Board requirements.

4.11. INVESTING IN THE EXPORT PROMOTION ZONES

Export promotion zones offer an attractive package for investors wishing to invest there. Apart from enjoying the incentives listed in Section 1.5 in this document, investors are also able to access workspaces and utilities (electricity and water). Investors wishing to engage in developer/operator activities, manufacturing and commercial activities can invest in the zones.

4.12. OPENING A BANK ACCOUNT IN KENYA

Foreign investors wishing to invest in Kenya can open bank accounts, which can be either in foreign or Kenyan currency. A foreign currency account is availed upon request by the applicant and helps cushion the customer from currency fluctuations.

Under the Proceeds of Crime and Anti-Money Laundering Act (No. 9 of 2010), banks are required to vet their customers before opening of the bank account. This entails doing due diligence on the following:

- a) The customer's identity;
- b) The identity of the beneficial owner;
- c) Purpose and nature of the business relationship;
- d) Business relationship and transactions undertaken throughout the course of that relationship to ensure that the transactions being conducted are consistent with the bank's knowledge of the customer, their business and risk profile, including, where necessary, the source of funds.

Once satisfied, the bank will proceed to open the account. Through this account, the account holder will be able to make financial transactions and even access loans and mortgage plans. Kenya repealed the exchange control laws in 1995 and has moved to a fully market-determined exchange rate system. The management of the foreign exchange was delegated to foreign exchange dealers (banks and foreign exchange bureaus). Authorized banks are licensed to buy, sell, borrow or lend in foreign currency or transact any other business involving foreign currency. They are also free to facilitate payments between Kenyan residents and non-residents and engage in spot money market and derivative foreign exchange deals. Forex bureaus, on the other hand, can engage in buying and selling foreign currency cash, and buying travellers' cheques, personal cheques, bankers' drafts and bank transfers. They may also sell travellers' cheques upon prior approval from the Central Bank of Kenya (<https://www.centralbank.go.ke>).

Generally, the Forex Bureau is only allowed to engage in spot foreign exchange transactions. The Kenya Bankers Association has also developed a portal where investors can calculate the cost of credit from banks. This enables investors to compare the different lending rates from the bank and make an informed decision on which bank they should approach for a credit facility. See <http://www.costofcredit.co.ke/>. See Annex IV for procedure to open a bank account in Kenya.

4.13. BUSINESS PERMITS

Business permits are permits issued by the county governments to allow one to trade in the county. The procedure to obtain a business permit across the counties is similar, though different fees will be charged for the business permit. The amount to be paid also varies according to the activity the investor will be carrying out and the number of employees. Investors are required to have business premises before they can obtain the business permit. See Annex V for the procedure to obtain a business permit in Nairobi County.

4.14. CLEARANCE CERTIFICATE FOR FIRE PREVENTION INSPECTION

Investors in the pharmaceutical manufacturing industry will also need to have a fire clearance certificate. The clearance helps regulate and ensure fire safety and prevention. It is valid for one year. The licence is issued by the relevant county government in which the business activity will take place. See Annex V for the procedure to obtain the unified business permit, which is inclusive of the fire clearance certificate.

4.15. FOOD HYGIENE LICENCE

The investor will also be required to obtain a food hygiene licence and the workers will be required to obtain a food handler's medical certificate. These certificates are issued by the county governments where the business activity will take place. For Nairobi County, the investor need not apply for a separate food hygiene licence, since it will be covered under the unified business permit as discussed in Section 4.13 of this document.

See Annex V for the procedure to obtain the unified business permit, which is inclusive of the food hygiene licence.

4.16. ENVIRONMENTAL IMPACT ASSESSMENT (EIA) LICENCE

An environmental impact assessment is a critical examination of impacts a project will have on the environment and measures to mitigate the negative effects while maximizing the positive ones. All industrial investors in the manufacturing industry are required to obtain an Environmental Impact Assessment Licence from the National Environment Management Authority (NEMA). They will be required to contract an environmental impact assessment expert who will draw the EIA report, then submit it to the authority for approval.

A list of licenced experts is available on the NEMA website (<https://www.nema.go.ke/>). See Annex IX for the procedure for the environmental impact assessment.

4.17. EFFLUENT DISCHARGE LICENCE

In addition to the Environmental Impact Assessment Licence, NEMA also requires that any operator of an industrial undertaking and operators of sewage systems acquire an effluent discharge licence. This licence will be acquired once the factory is in place, but before commencement of production. Application for the effluent discharge licence is made at the National Environmental Management Authority's offices.

4.18. LICENCE TO MANUFACTURE OR IMPORT EXCISABLE GOODS

All manufacturers and importers of excisable goods are required to obtain excisable goods licences. Excisable goods include fruit juices, wines and spirits, beer, cosmetics, plastic shopping bags and bottled water, among others. Investors involved in fruit processing are required to obtain this licence. The licence is issued by the Kenya Revenue Authority.

4.19. POWER CONNECTION

Kenya Power and Lighting Company (KPLC) is responsible for the distribution and retail of electricity in Kenya. The company buys electricity in bulk from all generating companies and retails it to customers. Investors in need of a power connection submit their application to Kenya Power and Lighting Company for processing.

4.20. WATER CONNECTION

Application for a water connection is made to Nairobi City Water and Sewerage Company, which is an ISO9001-certified institution that provides water and sewerage services to Nairobi residents. [See Annex VIII for the procedure to obtain a water connection.](#)

4.21. PHARMACY AND POISONS BOARD OF KENYA REQUIREMENTS

The PPB has developed guidelines for setting up pharmaceutical manufacturing facilities in Kenya. The guidance is intended to facilitate establishment of manufacturing facilities fit for production of good quality health products and technologies that meet international standards. [See Annexes XI and XII for Pharmacy and Poisons Board of Kenya requirements for setting up a pharmaceutical manufacturing facility and the relevant licences.](#)



ANNEXES

ANNEX I: STARTING A BUSINESS

A. Registering a foreign company in Kenya

The Companies Act under Section 995 provides for registration of foreign companies. A foreign company is a company that has been incorporated outside Kenya. Registration is done online through the [eCitizen portal](#).

REGISTRATION PROCEDURE

- 1) **Register with the eCitizen portal and conduct a name search.**
The name search costs KSh 150 and takes three hours to one day. The name is reserved for 30 days.
- 2) **Apply and pay for foreign company registration.**
The applicant will be required to fill in the [eCitizen](#) online forms and then download them for the directors to sign, then scan them back into the system.

REQUIREMENTS

- a) **Certified certificate of incorporation** – duly certified by a notary public from the county of origin;
- b) **Certified memorandum and articles of association** – duly certified by a notary public from the county of origin;
- c) **Passport** – for each foreign director and the local representative if foreign;
- d) **Passport photo** – for each foreign director and the authorized local representative.

For local representative if Kenyan:

- a) **PIN certificate;**
- b) **Identity card.**



The foreign company is required to have a local representative in Kenya, which can be either a Kenyan or a resident foreigner. Certified professionals capable of acting as local representatives such as lawyers and accountants are available and the investor can contact them directly via the associations' websites: <http://online.lsk.or.ke/> for lawyers or <https://www.icpak.com/cpa-directory/> for certified public accountant firms.

The cost of registration of the foreign company is **KSh 10,000**. Next, the certificate of compliance must be obtained. Upon uploading the [eCitizen](#)-generated forms and the above-listed requirements, the applicant will be issued with the certificate of registration and the list of shareholders (CR12) after 3–5 days.

B. Local company registration procedure

REGISTRATION PROCEDURE

- 1) **Register with the eCitizen portal using their account or the agent's account (lawyer or secretary):** www.ecitizen.go.ke (business registration service).
- 2) **Conduct a name search:** The proposed name must be searched and reserved online through [eCitizen](#). Names can only be reserved for 30 days with the prescribed fee of KSh 150. Name reservation takes three hours to one day.

- 3) **Apply and pay for company registration.** The applicant will be required to pay KSh 10,650 for the company registration, then fill in the eCitizen online forms and download them for signing, and then upload them back into the system. These forms include:
 - a) **Form CR1** – Application for registration of a limited company, unlimited company or a company limited by guarantee.
 - b) **Form CR2** – Memorandum for a company with a share capital or Form CR3 – memorandum for a company limited by guarantee.
 - c) **Form CR8** – Notice of residential address of the directors and company secretary if the company has a nominal capital of KSh 5 million or is a public company. The foreign directors are required to indicate their residential address at the country of origin and Kenyan directors must indicate their Kenyan addresses.
 - d) **Statement of nominal capital** – declaration of nominal capital of the company.
- 4) **Obtain certificate of incorporation and list of shareholders (CR12).**

Cost: KSh 10,650 for the company registration.

REQUIREMENTS

- a) **Proposed company name for name search approval.**
- b) **Objectives of the company.** The nature of business/activities the company shall undertake.
- c) **Full names of the shareholders.**
- d) **Full names of the directors if different from the shareholders.**
- e) **Postal addresses, e-mail addresses and telephone numbers of the shareholders and directors.**
The address of the directors can be foreign or Kenyan depending on the residency of the investor.
- f) **Number of shares to be held by each shareholder.**
- g) **Proposed physical address of the company and the directors.** The physical address includes the road name, the plot number, the town and the county. The proposed physical address must be Kenyan, as foreign investors will be incorporating the company in order to operate in Kenya. If the investor doesn't have a physical address at the time of incorporating the company, he or she can procure the services of an advocate to help in incorporating the company, then use the advocate's physical address as the initial address.
- h) **Copy of ID or passport biodata page of the shareholders and directors if they are foreigners.**
- i) **Passport photos of the shareholders and directors.**

C. Registration procedures for other business entities

Even though registration of the other forms of businesses entities are open to everyone, it is prudent for foreign investors to register a company to enable them to operate smoothly in Kenya. The company's certificate of incorporation is a mandatory requirement for most of the work permits applications. In addition, the company is considered to be a legal entity capable of suing and being sued in its own names.

BUSINESS NAME REGISTRATION IN KENYA

Business names can take the form of sole proprietorships or partnerships and are registered under the Business Names Act, Chapter 499. A business name means a name under which any business is carried on, whether in partnership or otherwise. The registration of business names has been migrated to the eCitizen platform, which allows applicants to make online applications.

REGISTRATION PROCEDURE

1) **Conduct a name search**

The proposed business name must be reserved pending registration. The application for reservation of a business name is made online at [eCitizen \(www.ecitizen.go.ke\)](http://www.ecitizen.go.ke) and accompanied by the prescribed fee of KSh 150.

2) **Apply for business name**

Once a name is searched for and reserved, the applicant(s) should complete the online application form in the [eCitizen portal \(www.ecitizen.go.ke\)](http://www.ecitizen.go.ke). The application fee for business name registration is KSh 850.

REQUIREMENTS

- a) Copy of passport of the proprietor or partners if they are foreigners;
- b) Passport photo of the proprietor/s; and
- c) Copy of PIN certificate of the proprietor/s or partner/s.

3) **Obtain certificate of registration, also referred to as BN3.**

LIMITED LIABILITY PARTNERSHIP

Limited liability partnership is registered under the Limited Liability Partnership Act (LLP), 2011. A limited liability partnership is a body corporate with perpetual succession with a legal personality separate from that of its partners. A partner is not personally liable for the partnership's obligations other than as a result of a wrongful act or omission by that partner, and partners are not liable for the wrongful act or omission of another partner.

Two or more persons (individuals or body corporates) may form a limited liability partnership by lodging with the Registrar of Companies a statement in the prescribed form. The statement must include the name of the partnership and the general nature of its proposed business, the address of its registered office, the name, nationality and address of each person who will be a partner, and the name, nationality and address of each person who will be a manager of the partnership. The name of the partnership must end with the words "limited liability partnership" or the abbreviation "LLP" or "llp". A limited liability partnership may be governed by a partnership agreement, but, if there is no such agreement or if there is an agreement that does not deal with a matter, it will be governed by the provisions set out in the First Schedule to the Act. A limited liability partnership must have at least one manager, who must be resident in Kenya.

REGISTRATION PROCEDURE

Registration of a limited liability partnership is done online through the [eCitizen portal \(www.ecitizen.go.ke\)](http://www.ecitizen.go.ke) Business Registration Service.

1) **Conduct a name search.**

2) **Apply for limited liability partnership registration.**

REQUIREMENTS

- a) Identity document or passport of and place of residence of each person who will be a partner of the partnership; or
- b) iCertificate of incorporation for corporates.

3) **Obtain certificate of registration.** The certificate is sent online through the eCitizen portal.

Cost: Name search and reservation is KSh 150 and registration fee is KSh 25,000. It takes 1–2 weeks to obtain the certificate of registration of the limited liability partnership.

ANNEX II: INVESTOR REGISTRATION AND OBTAINING INVESTMENT CERTIFICATE

1) **Apply to be a registered investor** at the Kenya Investment Authority offices.

REQUIREMENTS

- a) **Investment application form**, which is readily available on the KenInvest website (<http://www.investmentkenya.com/>).
- b) **Cover letter** addressed to the managing director of Kenya Investment Authority indicating the company's activities.
- c) **List of shareholders** (CR12).
- d) **Company registration certificate**.
- e) **Articles of association**. The company's articles of association may be determined by the shareholders independently or they may obtain a reference template from the Companies Act 2015, which provides model articles of association.
- f) **Proof of investment** of at least \$100,000, which can be either through money already in a Kenyan bank or assets purchased or imported towards initiating the project. In case of a bank statement, it should be in the sole names of the applicants or the company and must show that the amount to be invested by a foreign investor is at least \$100,000 or the equivalent in any other currency.

Upon submission of the application to be registered as an investor, KenInvest reviews the application and issues the applicant with an acknowledgment letter within 1–2 days.

2) **Apply for an investment certificate**.

REQUIREMENTS

Request letter – the letter should be addressed to the managing director of the Kenya Investment Authority requesting an investment certificate.

3) **Inspection of premises**.

KenInvest will inspect the premises to ascertain the existence of the project or the company and whether the housing use of the registered premises is consistent with the operation activities of the enterprise. Before the inspection, the authority notifies the investor of the scheduled date of the visit. (The investor can lease premises from the industrial parks or private persons or even buy land.)

The procedure for acquisition of land and leasing of premises is discussed in Annex VI.

4) **Obtain investment certificate**. The authority issues the applicant with the certificate after 1–2 days.

ANNEX III: FOREIGN TAXPAYER REGISTRATION THROUGH KENINVEST

- 1) **Apply for a director's PIN online at iTax:** <https://itax.kra.go.ke/KRA-Portal/>.
Upon completing the online form, the applicant will obtain a KRA acknowledgment receipt.
This will take 5–15 minutes.

REQUIREMENTS

Passport number and contact details such as e-mail address and physical address.

- 2) **Apply for investor facilitation and request PIN facilitation at the Kenya Investment Authority's offices.** The authority will assess the application and issue the applicant with an acknowledgment letter.

REQUIREMENTS

- a) **Investment application form.**
- b) **PIN acknowledgment receipt.**
- c) **Cover letter** addressed to the managing director of the Kenya Investment Authority requesting investor registration and foreign taxpayer PIN facilitation.
- d) **Company/business registration certificate.**
- e) **Memorandum and articles of association.**
- f) **Passport showing biodata and visa page.**
- g) **Proof of investment of at least \$100,000**, which can be either through money already in a Kenyan bank or assets purchased towards initiating the project. In case of a bank statement, it should be in the sole names of the applicants or the company and must show that the amount to be invested by a foreign investor is at least **\$100,000** or the equivalent in any other currency. [See Annex IV for the procedure to open a bank account and links to all the banks in Kenya where one can open a bank account.](#)
- h) **List of shareholders (CR12).**

IN ADDITION, FOR REPRESENTATIVES:

- a) **Agent's current practicing certificate** – the agent can be either an advocate or an auditor.
 - b) **Letter of authority** – for the designated representative of the branch – signed by the CEO or similar of the foreign company.
- 3) **Obtain endorsement letter.** This is issued within 1–4 days of the authority vetting the application. The applicant will then collect the endorsement letter from the authority's offices and submit to KRA for PIN processing.
 - 4) **Submit documents for PIN processing at the National Income Tax Support Centre.**

REQUIREMENTS

- a) PIN acknowledgment receipt – non-resident.
- b) Passport (original).
- c) Endorsement letter (original).

Applicants can be physically present or contract a Kenya Revenue Authority tax agent to submit the application for them. Tax agents are licensed representatives who are authorized to present documents for PIN processing, and even file tax returns for the company. Upon submitting the required documents, applicants will be issued with an individual PIN free of charge, which will allow them to apply for the company PIN.

- 5) **Apply for company PIN online through the iTax portal:** <https://itax.kra.go.ke/KRA-Portal/>. The applicant will be issued with a PIN acknowledgement receipt. When undertaking the PIN registration, the taxpayer is required to endorse the tax obligations that are applicable to the taxpayer. These include corporation tax, VAT, PAYE and income tax, etc.

REQUIREMENTS

- a) Director PIN.
- b) Certificate of incorporation/certificate of compliance of the company.
- c) Obtain company PIN. The PIN is sent to the applicant's registered e-mail.

ANNEX IV: OPENING A BANK ACCOUNT

- 1) **Identify the bank with which one wants to open an account.**
A list of banks operating in Kenya can be found on the Kenya Bankers Association website: <http://www.kba.co.ke/members.php>.
International banks offering China banking desks in Kenya include:
 - a) Stanbic Bank: <https://www.stanbicbank.co.ke/>
 - b) Absa Bank Kenya: <https://www.absabank.co.ke/>
- 2) **Identify the type of account one intends to open by going to the bank and enquiring about the services being offered, account types and charges.**
- 3) **Submit application for account opening.** The standard requirements for opening a bank account in Kenya include:

BUSINESS ACCOUNT REQUIREMENTS

- a) Company certificate of incorporation for local companies or certificate of compliance for foreign companies.
- b) Company KRA PIN.
- c) Directors' identity card copies or valid passport copy.
- d) Directors' passport photos.
- e) Memorandum and articles of association (CR2).
- f) Contact details, e.g. residential address, phone number and e-mail address.

PERSONAL ACCOUNT REQUIREMENTS

- a) Passport/identity cards.
- b) Passport photo.
- c) Personal identification number.
- d) Contact details.

Cost: The account opening varies depending on the bank.

Duration: It will take a week to open a business account, but the duration may vary depending on the bank.

ANNEX V: BUSINESS PERMITS – NAIROBI COUNTY

The County Government of Nairobi issues a business permit referred to as a unified business permit that consolidates five permits into one permit: the single business permit, fire clearance certificate, advertising signage, health certificate and food hygiene. Business entities that deal with consumables will be required to pay for the health certificate and a food hygiene licence in addition to the single business permit and fire clearance certificate. An advertising signage licence fee will only be applicable for all entities with advertising signage (300mm by 600mm or less).

1) **Apply for business permit at the Nairobi City Hall**

Annex building, Licencing Department. At the customer care office, the investor is issued with a business permit application form, which he/she must fill in.

REQUIREMENTS

- a) **Certificate of incorporation of the company.**
 - b) **Company PIN certificate.** Procedure for obtaining the company the PIN has been outlined in Annex III.
 - c) Identity card or passport of one of the directors.
- 2) **Submit the filled-in application form** and the attachments for assessment of fees to facilitate payment of permit fees. The licencing officer will assess the application form and indicate the fees to be paid.
 - 3) **Obtain invoice for business licence fees.** This is obtained from the data capturing counter at the Licencing Department. The investor is required to present the assessed application form. Duration: 5–45 minutes.
 - 4) **Pay the business permit fees.** This is done at the Nairobi County Cash Office. Once the investor pays the fees, he or she is issued with the unified business permit. This is an annual fee and the unified business permit is eligible for renewal upon expiry of the business permit on 31 December of each year. The fees for the unified business permit vary depending on the company's business activity and the number of employees.

Cost: For pharmaceutical manufacturing plant:

Trade licence – KSh 80,000

Fire permit licence – KSh 12,000

Health certificate – KSh 10,000

Food hygiene certificate – KSh 50,000

Advertisement – KSh 4,200

Registration fee – KSh 200

It takes 15 minutes to an hour to obtain the business permit.

Investors can also obtain the Nairobi unified business permit online at the Nairobi County self-service portal: <https://epayments.nairobi.go.ke/>.

The procedure to obtain the permit is detailed below.

1) **Register with the Nairobi self-service portal.**

REQUIREMENTS

- a) Passport number or identity card number.
- b) E-mail address.

- 2) **Apply for a unified business permit.** The investor will be required to register the business during the application.

REQUIREMENTS

- a) Registration certificate.
 - b) Kenya Revenue Authority PIN certificate.
 - c) Identity card or passport.
- 3) Submit application for assessment of fees at the county's offices.

The applicant will be issued with an invoice and then proceed to pay for the fees at the Nairobi City county offices, where they will be issued with the provisional unified business permit.

It takes 15 minutes to two hours to obtain the permit. *An investor can also obtain business permits for Nyeri, Kisumu and Mombasa Counties online through the eCitizen website: <https://www.ecitizen.go.ke/>. For the rest of the 44 counties, the procedure is similar to the one for Nairobi County, though the fees will vary.*

ANNEX VI: LAND TRANSFER PROCEDURE

- 1) **Identify the land the company wants to buy.**
Negotiate the price with the seller and get a copy of the title deed from the seller.
- 2) **Contract an advocate to conduct due diligence on the land.** See link for advocates in the county: <http://online.lsk.or.ke/>.
- 3) **The advocate will then proceed to conduct an official land search** at the Ministry of Lands and Physical Planning offices to identify the owner of the land and check whether the land has any encumbrances.
- 4) **The directors of the company and seller will then execute (sign) the sale agreement.**
- 5) **Obtain land registration documents from the seller.** The seller and his advocate are required to give the buyer's advocate the following documents.
 - a) **Consent to transfer land.** This consent is issued by the Ministry of Land and Physical Planning (for leaseholds) or the district land control boards if the land being transferred is freehold. There are 47 land control boards in Kenya: <https://eregulations.invest.go.ke/procedure/230/149/step/850?l=en>.
 - b) **Land rate clearance certificate issued by the county government to show that all rates accruing on the land have been paid.**
 - c) **Land rent clearance certificate from the Ministry of Lands and Physical Planning to indicate that the rent owed by the government has been paid.**
- 6) **Execution (signing) of land transfer document by both the seller and the buyer (company).** The seller is required to sign the transfer document and forward it to the buyer's advocate, together with the following: the original title of the parcel of land, land consent, certificate of incorporation/compliance of the company (if the seller is a company), Kenya Revenue Authority PIN for the company and the directors (see Annex III), identification document or passport for the directors of the company/individual, and three colour passport photos for each director.
NB: Non-citizens need to have a KRA PIN in order to effectively transfer land.

- 7) **The buyer's advocate will then submit the transfer document for valuation by the Ministry of Lands and Physical Planning offices.** A government valuer will value the land, then the buyer will be required to pay stamp duty.

Stamp duty is charged at:

- a) **For leasehold land:** 4% of the valued amount;
- b) **For freehold land:** 2% of the valued amount.

Do: One is required to obtain the Kenya Revenue Authority payment slip from the iTax portal (<https://itax.kra.go.ke/KRA-Portal/>) before one can proceed to make payments at the bank.

- 8) **Submit the transfer document to the Ministry of Lands offices for franking.** This can take 1–3 days.
- 9) **Upon franking of the documents,** the buyer's advocate will submit them for registration upon payment of KSh 500. The registration of the transfer takes 2–4 weeks.
- 10) **Upon registration of the transfer,** the certificate of title/lease will bear the name of the buyer, who will be considered as the legal and beneficial owner of the land.

ANNEX VII: CONSTRUCTION PERMITS IN NAIROBI COUNTY

- 1) **Contract an architect to draw the architectural drawings.** A list of licenced architects is available at <https://boraqs.or.ke/members/>.
- 2) **The architect registers with the Nairobi City eDevelopment permit system** (<https://ccn-ecp.or.ke/index.php>) and uploads the architectural drawings to the Nairobi eDevelopment permit system. The architect is required to upload the following documents:
 - a) **Architectural drawing.**
 - b) **Disclaimer form in case there is excess coverage.**
 - c) **Land survey plan.**
 - d) **Land rates clearance receipt.**
 - e) **Proof of land ownership.**
- 3) **Obtain construction payment invoice within 1–3 days.** This invoice is sent to the architect, who will then forward it to the investor for payment of the fees.
- 4) **Payment of the construction permits fees.** The fee is not standard and depends on the size and type of building being erected. See link for the fees: [https://kenya.eregulations.org/media/merged_document_15_1%20\(1\)_2.pdf](https://kenya.eregulations.org/media/merged_document_15_1%20(1)_2.pdf). The fee for a construction board, which must be erected before commencement of construction works, is KSh 30,000. The banker's cheque for the total fee should be addressed to the Nairobi City County and delivered to Nairobi County City Hall Cash Office.
- 5) **Obtain the architectural plans approval notification.** This is usually sent to the architect's e-mail or through the eDevelopment permit system. The approval takes 20–30 days before it can be issued, because the application has to undergo vetting.

- 6) **Submit the architectural drawings and the notification of approval for signature at the Nairobi City County offices:** Development Control Section.
It takes 1–3 days for the drawings to be signed, after which the architect can collect the authenticated drawings and approval. If the structure being constructed is a storeyed building, the investor will be required to contract a structural engineer to draw a structural plan, which must be approved by the county government.
- 7) **The structural engineer will work together with the architect** in order to upload the structural plans to the Nairobi eDevelopment permit system. It takes 1–3 days for the structural plans to be signed.
- 8) **Obtain the authenticated structural plans and approved certificate of structural design.**
During collection, the architect/structural engineer will be required to present the application reference number, which is issued when they submit the application.
- 9) **Register the project with the National Construction Authority:** The cost is nil.

REQUIREMENTS

- a) **Project contractor's practicing certificate.** A list of the registered contractors the investor can contract is available on the National Construction Authority's website: <http://nca.go.ke/new/src/searchregistered-contractors/>.
 - b) **The project consultants' practicing certificates** (e.g. engineer, architect and quantity surveyor, who must be duly registered by their respective professional bodies).
 - c) **Approved architectural and structural drawings.**
 - d) **NEMA licence (for commercial construction works).**
 - e) **Bill of quantities summary.**
 - f) **Developer KRA PIN (foreign taxpayer registration).**
 - g) **Signed contract/tender form/signed agreement** with the developer and contractor/consultants.
- 10) **Obtain preliminary compliance certificate to commence construction works.**

ANNEX VIII: WATER CONNECTION

- 1) **Submit application for water connection at the Nairobi City Water and Sewerage Company:** <https://www.nairobewater.co.ke/index.php/en/>.

REQUIREMENTS

- a) **Application form, which can be obtained from the Nairobi City Water and Sewerage Company.** The company is also required to pay KSh 2,500 for a survey and estimate of fees and attach the receipt of payment to the application form, stamped with a company seal.
 - b) **Company's certificate of registration.**
 - c) **Company PIN.**
 - d) **Land ownership documents.**
- 2) **Site visit to assess the connection cost.** Two to three weeks after the application has been received, Nairobi City Water and Sewerage Company will send a team to assess the connection cost.
 - 3) **Payment of the quoted connection price.** The connection fee for industrial customers is KSh 50,000.
 - 4) **Obtain water connection.** Once payment has been made, it will take an estimated 30 days to have a water connection.
 - 5) **Obtain notice of gazettelement from NEMA.** The authority will respond with a notice for gazettelement, which the applicant is supposed to submit to the Kenya Gazette for gazettelement.
At the Kenya Gazette, one is required to submit a forwarding letter requesting gazettelement and pay the following fees for the gazettelement.
 - a) **KSh 27,840** – for a full page of the gazette notice.
 - b) **KSh 13,920** – for a single column of the gazette notice.
 - c) **KSh 10,440** – for a three-quarter column of the gazette notice.
 - d) **KSh 6,960** – for half a column of the gazette notice.
 - e) **KSh 3,480** – for a one-quarter column or less of the gazette notice.The applicant is also supposed to advertise the notice in a public newspaper of wide circulation to allow the public to make their comments.
 - 6) **Submit evidence of gazettelement and advertisement of the notice.**
 - 7) **Obtain Environmental Impact Assessment Licence.**
A NEMA officer will randomly inspect the investment site before one obtains the Environmental Impact Assessment Licence within 30–45 days after the gazettelement.

ANNEX IX: ENVIRONMENTAL IMPACT ASSESSMENT LICENCE

- 1) **Submit terms of reference to National Environment Management Authority (NEMA) headquarters** and get approval within 10 days.
- 2) **Submit application through the online NEMA portal** (<http://portal.nema.go.ke>) and attach the study report and a copy of the EIA expert's practicing licence. Thereafter, submit hardcopies of the study to the NEMA headquarters accompanied by the following:
 - a) **EIA submission form** (original + two copies).
 - b) **Study report** (three originals).
 - c) **EIA expert practicing licence** (copy).
 - d) **Digital optical disk (CD) (original), which should contain the study report.**

ANNEX X: ELECTRICITY CONNECTION

- 1) **Submit application for supply of electricity.**

REQUIREMENTS

- a) **Enquiry for supply of electricity form**, which is readily available on the institution's website: www.kplc.co.ke.
- b) **Copy of ID/passport.**
- c) **Copy of PIN certificate.**
- d) **Route sketch map.**
- e) **Copy of title deed and land search documents** for owner of property (to support wayleaves consent). Wayleave is a permission granted to the KPLC by the land owner to enable them to construct and lay electric poles on the land.
- f) **Supply contract form (signed).** This form is readily available from the KPLC website.
- g) **Wiring certificates.** The investor will need to contract a licensed electrical technician who will install electrical wires in the building. A list of licensed technicians is available from the Energy Regulatory Authority's website: <https://www.epra.go.ke/services/electricity/>.

The cost of installations depends on the negotiations made between the investor and the licensed technician.

ADDITIONAL REQUIREMENTS FOR PREMIUM APPLICANTS

- a) **Scaled site plan** (preferably in soft copy AutoCAD or DWG format).
 - b) **Load schedule details.**
- 2) **Visit site to survey and design quotation.**

Kenya Power and Lighting Company (KPLC) locates the building using geographic information system (GIS) technology and makes the site visit in order to design the price quotation. Some of the key aspects that determine the price estimate that the client will receive include:

 - a) **Amount of power required for the building.**
 - b) **Existing infrastructure (poles and transformers).**
 - c) **Premises.** If the premise is within 600m of existing infrastructure, this considerably lowers the cost.
 - d) **Wayleaves clearance.**

- 3) **Pay the quoted amount or estimate.**
- 4) **Await the completion of the external works and meter installation and connection to supply.**

Duration: On average, it takes 97–165 days to get power supply.

Cost: The cost is dependent on the demand (kVA) required and the proximity of the premises to the existing electricity network. The cost will be determined after the application is made and a site visit is carried out to provide detailed information.

The current price of electricity is KSh 22.66 and 19.40 per kWh for household and businesses respectively (Sept. 2019).

POWER CONNECTION THROUGH KENINVEST FACILITATION

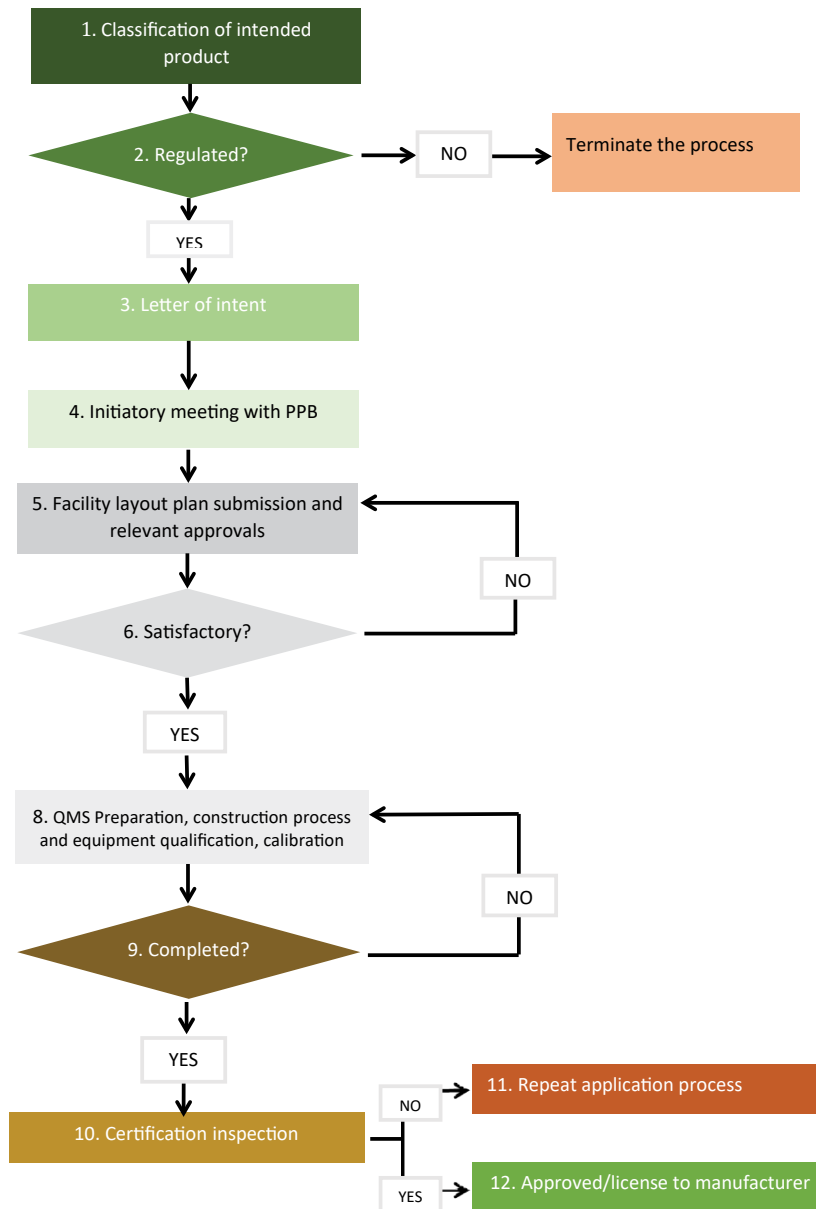
Kenya Investment Authority has an officer from the Kenya Power and Lighting Company whose mandate is to facilitate investors in obtaining power connection and promoting ease of doing business. This is done at **nil costs**. The procedure to obtain a power connection is similar to the one where the applicant goes to the KPLC offices.

The only difference is that, under KenInvest, the investor will be required to first apply for investor registration (see Annex II) and request the power connection, then the authority will proceed to facilitate the process of obtaining the power connection. It takes 72–159 days to obtain the connection.



ANNEX XI: PHARMACEUTICAL FACILITY SET-UP ROADMAP

Process flow chart for setting up a pharmaceutical manufacturing facility (PPB procedure)



Source: Pharmacy and Poisons Board of Kenya.

ANNEX XII: SPECIFIC LICENCES FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY

Product registration and other licensing requirements	
Regulatory authority	Pharmacy and Poisons Board (PPB)
Website of regulatory authority	http://pharmacyboardkenya.org
Annual licence to manufacture pharmaceutical products	KSh 50,000 per facility
Registration requirement (dossier format)	Common technical document (CTD) Product must be registered in Kenya before sale
Fees for product registration	\$1,000
Normal time taken for registration	12 months
Annual product retention fee (after registration of product)	\$300
Variation fee	\$200
Whether plant inspection is mandatory	YES Manufacturer must comply with GMP
GMP inspection fee	\$1,000

ANNEX XIII: USEFUL LINKS

Kenya Investment Authority (KenInvest)

UAP Old Mutual Tower, 14th floor, Upper Hill Road.
P.O. Box 55704-00200 City Square,
Nairobi, Kenya
Telephone: +254 (730) 104-200 or
+254 (730) 104-210
E-mail: info@invest.go.ke
Website: <http://www.invest.go.ke>

Ministry of Industry, Trade and Enterprise Development

Social Security House, Block A, 17th (Eastern Wing),
23rd floor (Eastern Wing)
P.O. Box 30418-00100, Nairobi, Kenya
Telephone: +254 20-2731531
E-mail: ps@industrialization.go.ke or
cs@industrialization.go.ke
Website: <http://www.industrialization.go.ke/>

Ministry of Health

Afya House, Cathedral Road
P.O. Box 30016-00100, Nairobi, Kenya
Telephone: +254-20-2717077
E-mail: ps@health.go.ke
Website: <http://www.health.go.ke>

Pharmacy and Poisons Board (PPB)

P.O. Box 27663-00506, Nairobi
Lenana Road Opp. DOD
E-mail: enquiries@pharmacyboardkenya.org,
info@pharmacyboardkenya.org
Website: <https://pharmacyboardkenya.org>

**Export Processing Zone Authority (EPZA)
Head office**

Administration Building, Viwanda Road,
Off Nairobi-Namanga Highway,
Athi River, Kenya

P.O. Box 50563, Nairobi 00200, Kenya

E-mail: info@epzakenya.com

Telephone: Safaricom:
+254 709 537 000,
+254 713 051172/3

Telephone: Airtel:
+254 786 683 222,
+254 733 683 222

Website: <https://epzakenya.com/>

Kenya Revenue Authority (KRA)

Times Tower Building
Haile Selassie Avenue

P. O. Box 48240–00100

Telephone: +254 20 281 0000

E-mail: callcentre@kra.go.ke

Website: <https://www.kra.go.ke>

Central Bank of Kenya

Haile Selassie Avenue

P.O. Box 60000–00200

Nairobi, Kenya

Telephone +254 20 286 1000,
+254 20 286 3000

E-mail: comms@centralbank.go.ke

Website: <https://www.centralbank.go.ke>

Kenya Medical Research Institute (KEMRI)

P.O. Box 54840 00200

Off Mbagathi Road. Nairobi, Kenya

Telephone: +254 722205901

E-mail: director@kemri.org

Website: <https://www.kemri.org>

Kenya Bureau of Standards (KEBS)

Popo Road, Off Mombasa Road

P.O. Box 54974–00200, Nairobi, Kenya

Telephone: + 254 (20) 694 8000

Mobile: +254 722 202 137
+254 734 600 471/2

E-mail: info@kebs.org@kebs.org

Website: <https://www.kebs.org>

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