



# Site Selection for Life Sciences Companies

in Sub-Saharan Africa

In association with



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December 2022

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# Foreword

## Building life sciences ecosystems in Sub-Saharan Africa

### Dear readers,

Over the last few years, Africa's demographic has grown rapidly. Various forecasts predict that the Sub-Saharan African population is set to double by 2050, contributing most to the global population.

To accommodate this growing population, Sub-Saharan countries need to quickly create hundreds of millions of jobs in the coming decades, improve their physical, legal and regulatory infrastructure and provide education for new generations.

Such growth plans can only be successful if they are backed by resilient and efficient healthcare services which provide the ever-growing population with quality medical treatments and products.

Against this background, the doctors, pharmacists, nurses and biologists needed to operate hospitals, distribution centers, warehouses, manufacturing sites and laboratories are in high demand. Yet, educating and retaining trained personal in sufficient numbers is not an easy task.

Innovative African entrepreneurs have reacted to the shortage of healthcare workers by creating e-health tools, some of which have attracted significant amounts in financing. This is a great start – but the continent also needs more regional drug development, clinical trial and manufacturing facilities in order to create local life sciences ecosystems which provide for quality jobs for trained life sciences and medical experts.

More local investments along the pharmaceutical, biological and medical devices manufacturing and distribution value chain will also have a positive impact on regional academic training of healthcare and life sciences professionals and will increase the resilience of local supply chains for medicines, vaccines and medical devices. Local manufacturing also opens the door to successful commercialization of medicines.

The importance of bringing manufacturing to Sub-Saharan Africa and creating life sciences ecosystems has been recognized by individual countries and international organizations such as the African Development Bank and African Union Development Agency.

To support manufacturing in Sub-Saharan countries, KPMG has compiled information for selected countries regarding business conditions, regulatory requirements, incentives and existing life sciences clusters which are supportive for investments into manufacturing facilities for pharmaceuticals, biologics and medical devices.

We hope that this publication will support the development of regional life sciences industry clusters and would be delighted to discuss how we can assist you in your plans to enter, expand or consolidate your life sciences operations in the region.



**Ignatius Sehoole**

Chairman  
KPMG Africa



**André Guedel**

Director  
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# Introduction

## International initiatives

Several international initiatives support the development of life sciences ecosystems and the manufacturing of medicines, vaccines and medical devices in Africa. Some recent examples are summarized below:

### African Development Bank

(AfDB, <https://www.afdb.org>)

In June 2022, AfDB approved the establishment of the **African Pharmaceutical Technology Foundation** to boost the continent's access to technologies needed to produce vaccines, medicines and other pharmaceutical products with a commitment package of around USD 3 billion over the next decade. The African Pharmaceutical Technology Foundation will prioritize technologies, products and processes focused primarily on diseases that are widely prevalent in Africa, including current and future pandemics. It will also build human and professional skills as well as a research and development ecosystem. The Foundation will support the upgrading of manufacturing plant capacities and regulatory quality to meet World Health Organization standards<sup>1</sup>.

### H3D-Foundation – IFPMA

The development of a framework to strengthen the African capacity for drug discovery and development is the goal of the partnership launched in September 2021 by the South African based H3D-Foundation (H3D-F, <https://h3dfoundation.org>) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA, <https://www.ifpma.org>). The two organizations will join forces to focus on driving capacity strengthening for drug discovery and development in Africa by scaling existing initiatives and identifying new development opportunities for young and mid-career scientists in the region<sup>2</sup>.

<sup>1</sup> African Development Bank – <https://www.afdb.org/en/news-and-events/press-releases/african-development-banks-board-approves-landmark-institution-establishment-african-pharmaceutical-technology-foundation-transform-africas-pharmaceutical-industry-52727>

<sup>2</sup> H3D-F – <https://h3dfoundation.org/partnershiplaunch>



### European Union

At the G20 Global Health Summit ([https://global-health-summit.europa.eu/index\\_en](https://global-health-summit.europa.eu/index_en)) in May 2021, the European Union pledged EUR 1 billion to an initiative to help create an enabling environment where vaccines can be manufactured in Africa, to tackle barriers on both the demand and supply side<sup>3</sup>. The “Team Europe” initiative focuses on manufacturing of vaccines, medicines and health technologies in Africa.

### European Investment Bank

In December 2020, the European Investment Bank (EIB, [www.eib.org](http://www.eib.org)) launched the first ever scheme to strengthen local production of active pharmaceutical ingredients in Africa and scale up drug manufacturing essential to improve public health. The EIB’s new EUR 50 million pharmaceutical investment initiative, initiated together with KENUP Foundation (<https://www.kenup.eu>), will contribute to reducing dependency on drug imports and address medical supply chain weaknesses linked to COVID-19. The program will improve the availability of specialist drugs and tackle supply chain challenges that currently damage public health across Africa<sup>4</sup>.

## Regulatory Environment

Efficient regulatory systems and competent national regulatory authorities (NRAs) are essential in order to boost manufacturing in the region. Several initiatives and organizations address these issues. Examples include:

### African Medicines Agency

In February 2019, the African Union decided to establish a specialized agency dedicated to improving access to quality, safe and efficacious medical products in Africa. The African Medicines Agency (AMA, <https://www.nepad.org/microsite/african-medicines-agency-ama>) will be headquartered in Rwanda<sup>5</sup>. It has been mandated by 17 member states thus far to coordinate national and sub-regional regulatory systems for medical products, provide regulatory oversight and promote cooperation and harmonization in Africa.

### World Health Organization

Effective regulatory systems are an essential component of health systems and contribute to desired public health outcomes and innovation. To identify strengths and areas for improvement and facilitate the formulation of an institutional development plan (IDP), the World Health Organization (WHO) has developed its **Global Benchmarking Tool** (GBT, <https://www.who.int/tools/global-benchmarking-tools>) which objectively evaluates the quality and efficiency of NRAs.

The GBT applies the concept of “maturity level”, allowing WHO and regulatory authorities to assess the overall “maturity” of the regulatory system on a scale of 1 (existence of some elements of regulatory system) to 4 (operating at advanced level of performance and continuous improvement).

Several NRAs of Sub-Saharan countries have already been ranked by the GBT including Ghana, Nigeria, Tanzania and Egypt.

### African Medicines Regulatory Harmonization program

The African Medicines Regulatory Harmonization program (AMRH, AMRH Home | AUDA-NEPAD- AMRH) was launched in 2009 as a response to challenges faced by national medicine regulatory authorities (NMRAs) in Africa. The aim of the program is to facilitate and coordinate the harmonization of medicines regulation and improve access to quality, safe, efficacious and affordable medicines in Africa as part of the broader African Union Framework on Pharmaceutical Manufacturing Plan for Africa (PMPA, <https://www.nepad.org/publication/pharmaceutical-manufacturing-plan-africa>).

<sup>3</sup> EU – [https://ec.europa.eu/commission/presscorner/detail/en/fs\\_21\\_2601](https://ec.europa.eu/commission/presscorner/detail/en/fs_21_2601)

<sup>4</sup> EIB – EIB launches EUR 50 million Africa pharmaceutical manufacturing initiative

<sup>5</sup> Africanews – <https://www.africanews.com/2022/07/18/au-selects-rwanda-to-host-hq-of-new-african-medicines-agency/>

## International life sciences and healthcare research collaboration networks

Several international research organizations are present in Sub-Saharan regions. They significantly contribute to the development of local life sciences ecosystems. Some examples are described below:

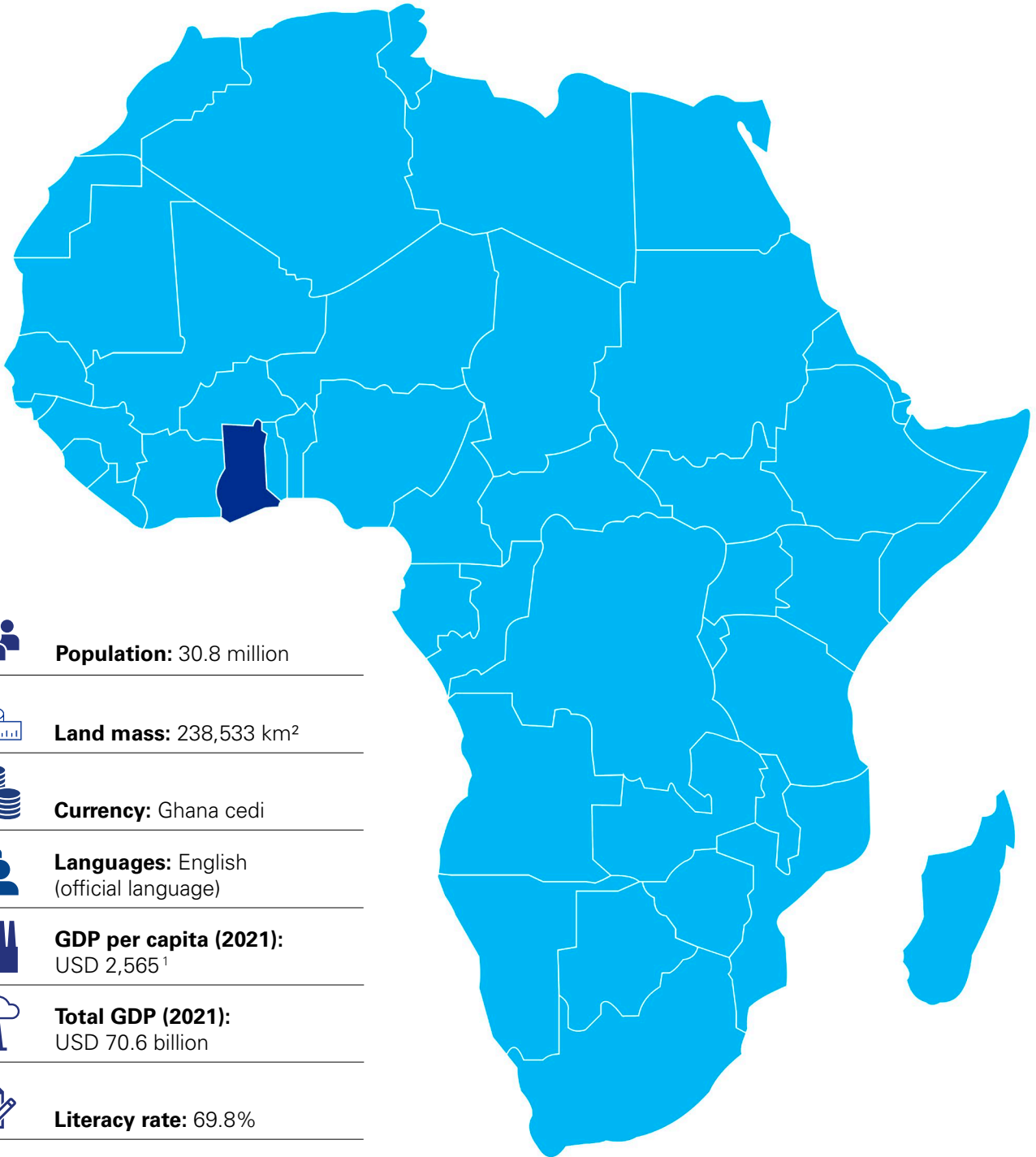
- **PATH** aims to improve people's health around the world by advancing technologies, strengthening systems and encouraging healthy behavior, with the main focus on R&D in various African countries (<https://www.path.org/where-we-work/#africa>).
- The **Swiss Tropical and Public Health Institute** (<https://www.swisstph.ch/en/>) is a leading institute in global health with long-term partnerships in low- and middle income countries, e.g. Tanzania and Côte d'Ivoire. Their expertise ranges from clinical trials and diagnostics to consultancy and project implementation
- The **Institut Pasteur** (<https://www.pasteur.fr/en/institut-pasteur/institut-pasteur-throughout-world/pasteur-network>) has a large network of research collaboration across mainly West African countries.
- The **International Development Research Centre** (IDRC, <https://www.idrc.ca/en>) invests in research in developing countries. Regional offices the African continent are located in South Africa, Kenya, Senegal and Jordan.
- The **UK Science & Innovation Network in South Africa** (<https://www.gov.uk/world/organisations/uk-science-innovation-network-in-south-africa>) fosters partnerships between academics and researchers, both at individual and institution level in South Africa.
- **Deutsche Forschungsgemeinschaft** (<https://www.dfg.de/https://www.dfg.de/en/index.jsp>) supports research collaboration with universities in selected African countries.

## Regional health federations

Private and public sector actors from the healthcare sector have organized themselves in regional and continent-wide organizations. Some examples are set out below:

- **African Health Federation** (<http://africahf.com/about-us>) is an umbrella organization of the private health sector in Africa.
- The **West African Health Federation** (WAHO, <https://www.wahooas.org/web-ooas>) is a specialized institution of the Economic Community of West African States (ECOWAS). Its mandate includes support for the launch of laboratories for local production of vaccines, medicines manufacturing and quality control in the region.
- The **East Africa Health Federation** (EAHF, <https://eahf.net>) comprises regional health private sector health federations.

# Ghana



**Population:** 30.8 million



**Land mass:** 238,533 km<sup>2</sup>



**Currency:** Ghana cedi



**Languages:** English  
(official language)



**GDP per capita (2021):**  
USD 2,565<sup>1</sup>



**Total GDP (2021):**  
USD 70.6 billion



**Literacy rate:** 69.8%



**Moody's credit rating:** Caa1



**System of government:** Multi-party democracy (presidential)



An aerial photograph of a city in Ghana, showing a mix of modern and traditional architecture. A wide, multi-lane road runs diagonally from the bottom right towards the center. To the left of the road, there are several large buildings, including a prominent one with a blue glass facade and another with a red roof. The city extends into the background under a blue sky with scattered white clouds. A semi-transparent dark grey box in the bottom left corner contains white text.

**Ghana is the 2nd  
country in Africa  
to attain a ML3  
regulatory  
system.**



# Snapshot of Ghana

Ghana is a country of 31 million people with a fast-growing, young, globally and digitally connected population<sup>2</sup>. Despite increasing taxes and legal uncertainties, Ghana remains a good choice as a regional hub for businesses due to its political stability, relatively advanced infrastructure and as host of the secretariat to the African Continental Free Trade Area. Ghana is expected to benefit from high prices of gold and oil in 2022<sup>3</sup>.

The nominal GDP for 2021 is estimated at USD 70.6 billion and the GDP growth for 2022 is projected to remain at a marginal rate of 5.2%. The growth is driven by the service sector – Ghana's digital, financial services, education and franchising sectors are growing fast. Services remain the largest contributor to GDP, accounting for 50%, followed by industry and agriculture at 29% and 21%, respectively.

Ghana's pharmaceutical industry is dependent on foreign inputs and finished pharmaceutical products. As in most African countries. Roughly 70% of pharmaceutical demand is met by imports, mainly from India and China, with local production accounting for 30%.

Ghana has ambitious plan for industrialization and the AfCFTA trade regime agreement makes Ghana a potential entry point for foreign companies for the whole West African Sub-region, or even the continent at large.

## International rankings

- Ghana is ranked 9th among 47 countries in the SAA region in the 2022 Index of Economic Freedom (<https://www.heritage.org/index/country/ghana>). Its score is above the regional average but below the world average.
- According to World Health Organization (WHO), Ghana has become the second country in the WHO African Region to attain regulatory system "Maturity Level 3", the second highest in the four-tiered WHO classification of national medicines regulatory systems. Ghana and Tanzania were the first two countries in the WHO

African Region's 47 countries to have achieved a Level 3 ranking<sup>4</sup> followed by Nigeria and Egypt. Evaluations of the Ghana Food and Drugs Authority – the national regulatory body for medicines – were carried out over multiple years using the WHO Global Benchmarking Tool. This will ensure that quality, safe and efficacious medicines are available to African citizens.

## International connectivity

- Ghana is a member and host country of the African Continental Free Trade Area (AfCFTA, <https://au-afcfta.org>). Along with Rwanda, Cameroon, Egypt, Kenya, Mauritius, and Tanzania, Ghana will take part in trading goods under the AfCFTA on a pilot basis.
- Ghana is also part of the West African Health Organization (WAHOAS, <https://www.wahooas.org>)

## Key processes to establish a pharmaceutical manufacturing plant

### Registration with the Registrar General's Department (RGD, <https://rgd.gov.gh>)

The RDG is the department in Ghana authorized to undertake the registration or incorporation of businesses in Ghana. A company can be registered as a company limited by shares, unlimited by shares, or limited by guarantee. Pharmaceutical companies are usually registered as a company limited by shares. The company must appoint at least two directors – at least one of which must be ordinarily resident in the country – a qualified auditor and a qualified company secretary.

### • Registration with the Ghana Revenue Authority (GRA, <https://gra.gov.gh>)

A company carrying out business in Ghana will be liable to various taxes including corporate income tax, value added tax (VAT), employment income tax and withholding tax. Therefore, registration with the GRA helps the company to comply with its tax obligations.

### • Registration with Ghana Investment Promotion Centre (GIPC, <https://gipc.gov.gh>)

All foreign or foreign local joint investors are mandated to register their businesses with the GIPC. Where the company is a joint venture with Ghanaians, minimum foreign equity of USD 200,000 in cash or goods is required. In the case of a wholly foreign owned

<sup>1</sup> Ghana Statistical Service

<sup>2</sup> US Commercial Service Ghana <https://www.trade.gov/ghana>

<sup>3</sup> Economic Report 2022, Swiss Embassy Ghana <https://www.s-ge.com/ko/node/1659>

<sup>4</sup> WHO – <https://www.who.int/about/accountability/results/who-results-report-2020-mtr/country-story/2020/ghana-s-regulatory-system-achieves-a-critical-milestone>

company, minimum foreign equity of USD 500,000 in cash or goods is required. However, if the company is into trading (buying and selling imported goods and services), minimum foreign equity of USD 1,000,000 is required.

- **Registration with the Food and Drugs Authority** (FDA, <http://www.fdaghana.gov.gh>)

The FDA is the main public institution mandated to register any drug and approve it for production and consumption in Ghana. The FDA has developed specific guidelines for the development of drugs through clinical trials to the stage where it is ready for commercial production. Approval is also required for all drugs imported into the country.

- **Registration with other relevant pharmaceutical licensing bodies**

Depending on the planned activities there are other institutions such as the Pharmaceutical Manufacturing Association of Ghana (PMAG), the Pharmacy Council and the Pharmaceutical Society of Ghana (PSGH), which all regulate the industry. Manufacturers require a license from the Food and Drug Authority, while retail and wholesale pharmacies require license from the Pharmacy Council.

- **Registration with the Environmental Protection Agency** (EPA, <http://www.epa.gov.gh/epa>)

The Environmental Protection Agency is the leading public body for protecting and improving the environment in Ghana. A manufacturing company will be required to prepare an environmental and social impact assessment (ESIA) report to be approved by the EPA.

## Tax and other incentives for pharmaceutical manufacturing activities

The pharmaceutical industry remains a top priority for the government. To encourage pharmaceutical market growth, the Ghana National Chamber of Pharmacy (GNCoP, <https://gh.linkedin.com/company/gncopharma>), with funding from foreign, commonwealth and development organizations, has created a support package. The fund will be used to provide grants to pharmaceutical manufacturers and for distributors and consulting firms within the pharmaceutical sector. Also, the government has extended the list of medicines to 49 drugs that can only be sold and produced locally as per the Executive Instrument on Restricted List of Medicines, 2016 (E.I. 181).

The following tax incentives are available:

- Pharmaceuticals listed under Chapter 30 of the Customs Harmonised System supplied in Ghana are exempt from value-added tax and import duties
- The supply or import of the active ingredients and selected inputs for the manufacture of pharmaceuticals as determined by the Minister of Health and prescribed in regulations are exempt from value-added tax and import duties
- The import of selected drugs or pharmaceuticals as determined by the Minister of Health or regulations is exempt from value-added tax and import duties
- There is a corporate income tax rebate of between 12.5% and 50% for manufacturing pharmaceutical companies if they are located outside Accra/Tema
- Tax losses can be carried forward for five years for pharmaceutical manufacturing companies
- There is exemption from import duties on imported machinery for manufacturing when the company is registered with GIPC

## Key players in the life sciences industry

The country's pharmaceutical sector comprises local, international and multinational players with the majority situated in Greater Accra and the rest in Ashanti and Brong-Ahafo regions. There are currently 38 pharmaceutical manufacturing units in Ghana, of which about 20 are actively involved in manufacturing formulations, with domestic companies accounting for 30% of the country's pharmaceutical market according to the GIPC. There is a presence of multinational pharmaceutical companies in Ghana and some work in collaboration with local firms through domestic partnerships.

### Examples of activities of international and global life sciences companies in Ghana

In June 2022, **Novartis** announced that the company is partnering with the American Society of Hematology (ASH) to roll out an app in six sub-Saharan African countries to track babies who receive a diagnosis of sickle cell disease (SCD) through newborn screening. The app is already in use in Ghana, where it works to collect and store screening results even when there is limited internet connection. This means that babies can receive clinical referral sooner and have timely access to care<sup>5</sup>.

**Kinapharma** (<https://kinapharma.com>), a large Ghana-based manufacturing and distribution pharma company producing different medications, i.e., painkillers, anti-hypertensions, has successfully launched an internationalization strategy and now serves regional markets in Nigeria, Sierra Leone and Liberia.

<sup>5</sup> Novartis announces partnership with the American Society of Hematology to fight sickle cell disease in Sub-Saharan Africa | Novartis



In 2019 **Dannex Ayrtan Starwin PLC** (<https://dasplcgh.com/about-us>) under the trade name DAS pharmaceutical company was incorporated and subsequently listed on the Ghana Stock Exchange.

### Pharmaceutical parks

Currently under construction in the Greater Accra Region is the USD 321 million, 60-ha pharmaceutical plant in the **Dawa Industrial Zone** (<https://diz-ghana.com>)<sup>6</sup>. The pharmaceutical plant, which is certified to World Health Organisation (WHO) Good Manufacturing Practices (GMP), is expected to take about 14 months to complete.<sup>7</sup> Tenants would be a consortium led by **DEKS Vaccines Limited**, which would include a “fill and finish” site that imports components of COVID-19 mRNA vaccines for processing, packaging and distribution nationwide and within the sub-Saharan region. With funding support of EUR 5 million from the German Development Cooperation and seed money of USD 25 million from the government, the plant is expected to be fully operational by January 2024 to produce the country’s first COVID-19 vaccines.

### Clinical trials

The Clinical Trials Department of the FDA is responsible for authorization and monitoring of clinical trials. The Department is designated as a Regional Centre of Regulatory Excellence (RCORE) in clinical trial regulation in Africa and has trained over 50 African regulators in clinical trial regulation as a result of this. The Department aims to implement the appropriate and modern regulatory measures to achieve the highest standard for design, conduct, recording and reporting of clinical trials in Ghana.

### Health tech

Ghana is one of the countries in West Africa with a high penetration of mobile phones. This offers a way to address healthcare gaps for people living in remote areas of the country by providing healthcare innovations through mHealth. Examples of Ghana-based health tech companies are:

**MPedigree** (<https://mpedigree.com>) is a global leader in the use of mobile and web technologies securing products against faking, counterfeiting and diversion. The company is active in 12 countries, protecting pharmaceutical companies and consumers from purchasing fake medicine.

Founded in 2013, Ghanaian health tech startup **mPharma** (<https://mpharma.com>) is building a network of community pharmacies across Africa as it plans to be the go-to primary

healthcare service provider for millions of people residing in the region. In January 2022 it raised USD 35 million<sup>8</sup>.

### Infrastructure and logistics

Ghana has two major international airports – **Kotoka International Airport** and **Kumasi International Airport** – and several secondary domestic airports such as Ho, Tamale and Wa. Currently, 38 airlines operate in Ghana, connecting directly to 30 different destinations around the world.

Ghana’s transport infrastructure has undergone significant upgrades in recent years, boosting the country’s logistics, tourism and industrial capacity. Compared to other lower-middle-income African countries, Ghana ranks ahead of several other low-income economies in Africa.

Access to the internet is not a challenge in Ghana. The World Bank, in 2020<sup>9</sup>, estimated that more than 58% of the total population use internet in Ghana. There are also 59 secure servers per one million population. Moreover, about 86%<sup>10</sup> of the population have access to electricity in Ghana. Overall, the quality of infrastructure and the level of internet penetration makes Ghana a preferred choice for both pharmaceutical research and manufacturing.

### Organizations and associations

The following bodies play a significant role in the regulation of pharmaceutical industry:

#### Food and Drugs Authority

(FDA, <https://fdaghana.gov.gh/index.php>) is the national regulatory body responsible for the regulation of food, drugs, food supplements, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products as well as the conduct of clinical trials protocols.

The Registration and Inspectorate Division of the FDA is responsible for the evaluation of medicine registration applications leading to the registration of medical products. The Safety Monitoring and Clinical Trials Division ensures the safety of regulated products.

<sup>6</sup> <https://www.ghanaweb.com/GhanaHomePage/business/Investors-target-local-pharma-market-1518470>

<sup>7</sup> Ghana: Construction of Ghana’s First Vaccine Manufacturing Plant Begins July – allAfrica.com

<sup>8</sup> <https://techcrunch.com/2022/01/05/mpharma-raises-35million-in-round-participated-by-tinder-co-founders-jam-fund-bharti-executive/>

<sup>9</sup> World bank: <https://data.worldbank.org/indicator/IT.NET.USER.ZS?locations=GH>

<sup>10</sup> World bank: <https://data.worldbank.org/indicator/EG.ELC.ACCS.ZS?locations=GH>

The drug registration process in Ghana takes between six and 18 months, which is relatively short compared with other countries in Africa.

The **Pharmacy Council** (<https://pcghana.org/>) is tasked with regulating the practice of pharmacy in Ghana. The Council issues two types of pharmacy licenses: wholesale and retail. The Council requires all pharmacies to be supervised by registered pharmacists in good standing with the Council before being approved, amongst other things. The process is as follows;

- **Application:** A body corporate that has employed a registered pharmacist or any other medical treatment center that has engaged a registered pharmacist shall apply to the Pharmacy Council to establish a pharmacy. Such applications should specify the proposed location.
- **Processing:** All pharmacy applications shall be made through the office of the Registrar of the Pharmacy Council. Upon receipt of the application an authorized officer of the Pharmacy Council shall inspect the proposed site for the pharmacy. Approval granted by the Council is valid for a specified period of time. It must be noted that approval of an application does not constitute authorization to commence business until all conditions and requirements for the issuance of license are fulfilled. The Council reserves the right to consider other applications for the same area after the period specified in the approval has elapsed.
- **Interview:** The superintendent registered pharmacist may be invited for an interview on submission of the application – where applicable, together with the proprietor, directors or partners, or an authorized representative of the company

**Pharmaceutical Manufacturers Association of Ghana (PMAG)**, (<http://www.pmaghana.org/our-purpose>) is made up of pharmaceutical manufacturing companies in Ghana and has the following purpose:

- Ensure quality of medicines supplied to patients
- Ensure that the supply of medicines is within the law
- Ensure that the medicines prescribed to patients are suitable
- Advise patients about medicines, including how to take them and what reactions may occur, and answer patients' questions
- Supervise the medicines supply chain and ensure pharmacy premises and systems are fit for purpose
- Advise other healthcare professionals about safe and effective medicines use, and safe and secure supply of medicines

PMAG promotes pharmaceutical manufacturing by enabling a favorable economic, regulatory, and political

environment that enables the industrial players to meet the pharmaceutical needs of the nation.

### Pharmaceutical Society of Ghana

(PSGH, <https://psgh.societymanager.org/home>) is a society made up of registered pharmacists in the country. The Society aims to provide accessible, affordable, sustainable, and quality pharmaceutical services to all through professionalism, continuous development, welfare, leadership and collaboration with relevant stakeholders.

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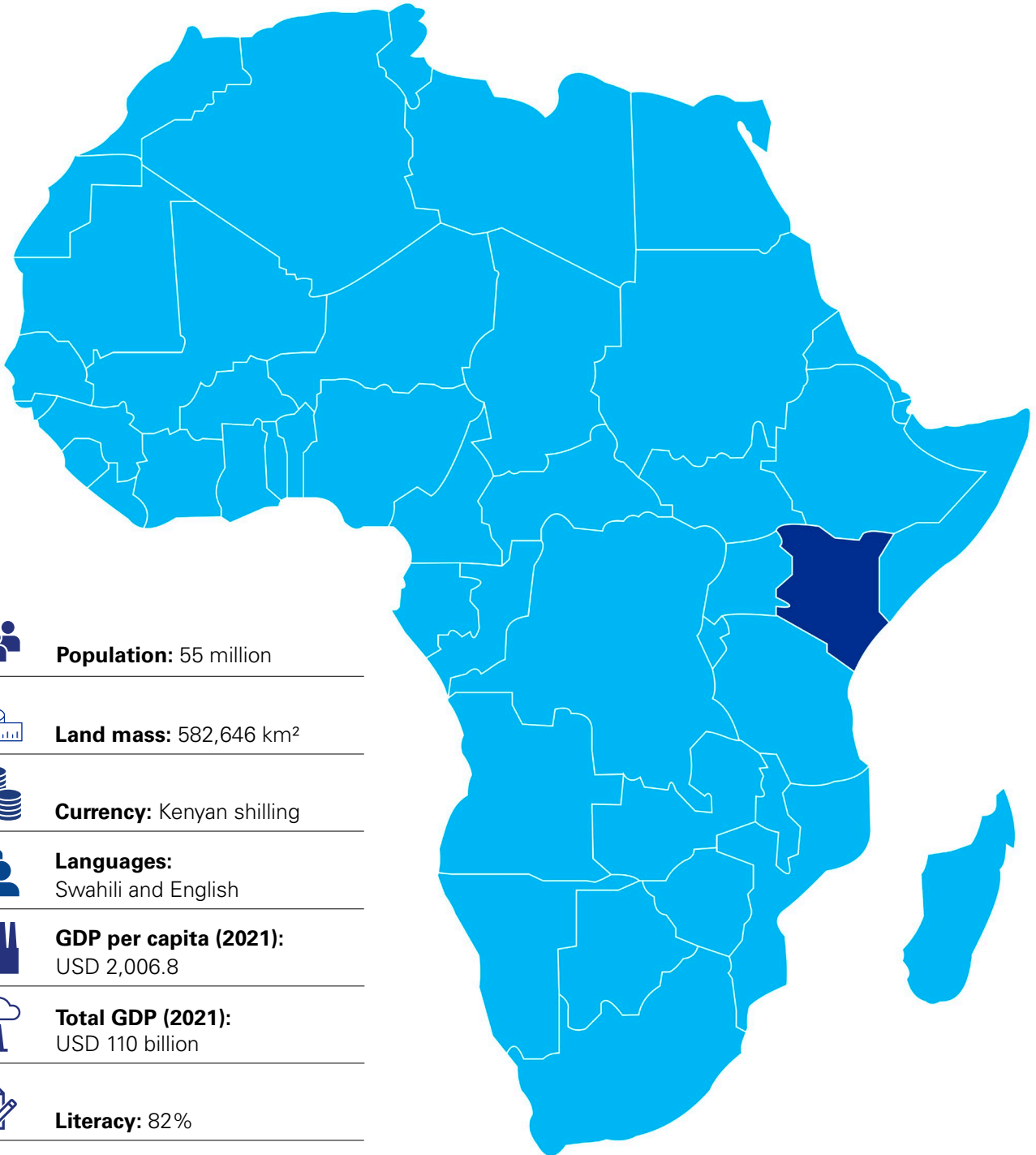
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<https://home.kpmg/gh/en/home.html>

# Kenya



**Population:** 55 million



**Land mass:** 582,646 km<sup>2</sup>



**Currency:** Kenyan shilling



**Languages:**  
Swahili and English



**GDP per capita (2021):**  
USD 2,006.8



**Total GDP (2021):**  
USD 110 billion



**Literacy:** 82%



**Moody's credit rating:** B



**System of government:**  
Presidential





**Kenya is the  
leading East  
African country for  
pharmaceutical  
production.**



# Snapshot of Kenya

Kenya is one of the fastest growing economies in East Africa. With a population of 55 million people, Kenya has a significant urban population that is young, well-educated and English-speaking. This, along with the increasing diversity of industries and strong trade links with both neighboring and overseas countries, makes Kenya a natural platform for foreign companies looking to enter the region<sup>1</sup>.

Kenya is classified as a lower-middle income country with a GDP of USD 110 billion and constitutes approximately 40% of the total East African Community. Striving to further develop the country, the government introduced “Kenya Vision 2030” in 2008 – a development strategy aiming to transform Kenya as a newly industrialized middle-income country by 2030<sup>2</sup>.

To achieve this goal, the development of a domestic life sciences manufacturing industry is a crucial component of this strategy. Kenya is the second-largest foreign direct investment (FDI) recipient in East Africa. The leading nations with FDI to Kenya are the People’s Republic of China, the Netherlands and the United Kingdom of Great Britain and Northern Ireland.

## International rankings

- **The Ibrahim Index of African Governance** (<https://iiag.online>) ranks Kenya as clear leader among the East African countries in terms of Overall Governance, Security of Law, Participation Rights and Inclusion, Foundation for Economic Opportunities and Human Development.
- According to the **Index of Economic Freedom** (<https://www.heritage.org>), Kenya is ranked 28th in terms of economic freedom among 47 countries in the Sub-Saharan Africa region.
- According to the **World Bank Group**, Kenya also compares favorably to neighboring countries and within Africa on crucial parameters such as

infrastructure development, electrification rate and trained labor.<sup>3</sup>

## International connectivity

- Kenya is a member of several regional economic and trade cooperations in Africa, including the East African Community (EAC, <https://www.eac.int>) and Common Market for Eastern and Southern Africa (COMESA, <https://www.comesa.int>). Kenya is also a signatory to the African Growth and Opportunity Act (AGOA)<sup>4</sup>.
- Kenya was among the first countries to sign the African Continental Free Trade Area Agreement (AfCFTA, <https://www.afcfta.org>), which became effective in May 2019, and has recently launched a national strategy to fast-track its implementation.
- Kenya is also member of the East African Healthcare Federation (EAHF, <https://eahf.net>).

## Key processes to establish a pharmaceutical manufacturing plant

The **Pharmacy and Poisons Board** (PPB, <https://web.pharmacyboardkenya.org>) is responsible for regulating medical products and health technologies and has developed guidance to facilitate the setting up of pharmaceutical manufacturing facilities in Kenya.

**Processes flow** chart of the necessary steps for setting up of a pharmaceutical manufacturing facility in Kenya<sup>5</sup> (see page 19).

## Other important agencies include

**Kenya Medical Supplies Authority** (KEMSA, <https://www.kemsa.co.ke>) is a state corporation under the Ministry of Health whose mandate is to procure, warehouse and distribute drugs and medical supplies for prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals.

**The Kenya Bureau of Standards** (KEBS, <https://www.kebs.org>) is the government regulatory body, under the Ministry of Trade and Industrialization, mandated to prepare standards relating to products, measurements, materials, processes, etc., and promoting them at national, regional and international levels.<sup>6</sup>

<sup>1</sup> Switzerland Global Enterprise <https://www.s-ge.com/en/article/global-opportunities/20213-c6-kenya-tech-hub-flint1>

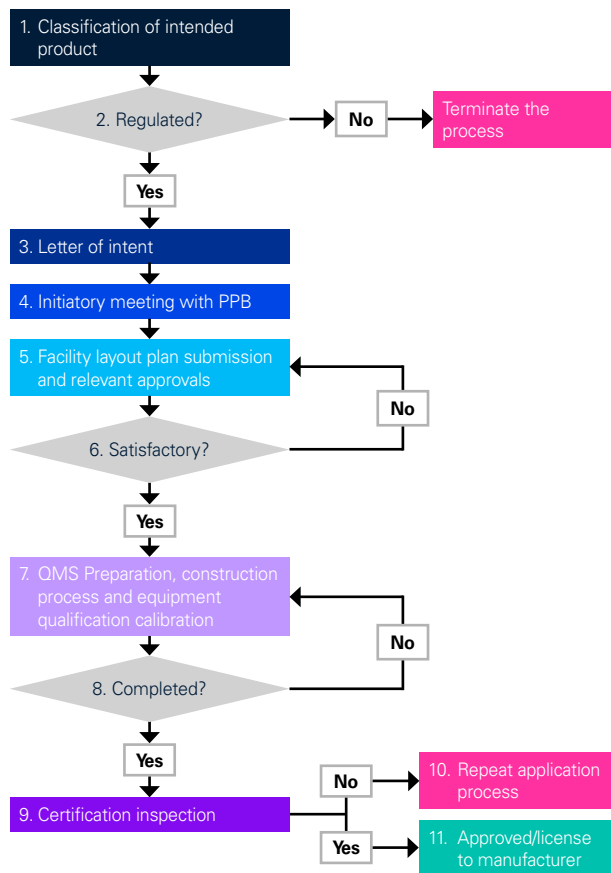
<sup>2</sup> Kenya President’s office: Big Four has not replaced Vision 2030 | Kenya Vision 2030

<sup>3</sup> World Bank Group: GCI 4.0: Ease of finding skilled employees – TCdata360 ([worldbank.org](https://www.worldbank.org))

<sup>4</sup> United Nations: UNCTAD/ITCD/TSB/2003/1

<sup>5</sup> Kenya Invest: <http://www.invest.go.ke>

<sup>6</sup> Kenya Bureau of Standards: [https://www.kebs.org/index.php?option=com\\_content&view=article&id=6&Itemid=255](https://www.kebs.org/index.php?option=com_content&view=article&id=6&Itemid=255)



Source: Pharmacy and Poisons of Kenya

## Tax and other incentives for manufacturing activities

The **Ministry of Industrialization, Trade and Enterprise Development** (<https://www.industrialization.go.ke>) is in charge of creating a globally competitive business environment for investors through fostering appropriate policy, legal and regulatory frameworks.

Kenya is a large recipient of foreign direct investment (FDI). In 2021, FDI flows to Kenya came to about USD 450 million<sup>7</sup>. In order to cluster foreign investments in geographically defined areas, Kenya has established **two types of industrial zones** across the country with different types of incentives as show below:

- Special economic zones (SEZ) focus on manufacturers for the domestic market. SEZs are located in Mombasa, Lamu and Kisumu.
- Export processing zones (EPZs) aim to attract manufacturers for export. There are currently more than

40 such zones in Nairobi, Voi, Athi River, Kerio Valley, Mombasa and Kilifi.

### The government offers attractive incentives for companies establishing operations in these zones<sup>8</sup>:

#### Special economic zones authority (SEZA) incentives

- 10-year tax holiday
- 15% corporate tax for another 10 years
- Duty and VAT exemption
- Exemption from stamp duty
- Exemption from withholding tax

#### Export processing zones authority (EPZA) incentives

- Exemption from corporate income tax for 10 years
- Exemption from VAT and customs duties on import of machinery and raw material
- 10 year withholding tax holiday on dividend
- 100% investment deduction on new investment on EPZ building

#### Incentives for locally manufactured pharmaceutical products

Public and private purchasers offer attractive mark-ups for locally manufactured products, while local products benefit from faster timelines for product registrations:

- **Public procurement**

KEMSA offers a 15% price preference for locally produced products.

- **Private procurement**

MEDS offers a price preference of 10% for local products.

- **Product registration**

Faster timelines for registrations of locally manufactured products

#### Indirect tax exemptions

Against the backdrop of COVID-19, the Kenyan government has been keen on driving affordable healthcare by amending tax tariffs on pharmaceutical products. The following items are VAT exempt:

- Plant and machinery for use by manufacturers of pharmaceutical products upon recommendation of the Cabinet Secretary
- Medical oxygen supplied to registered hospitals
- Urine bags, adult diapers, artificial breasts and colostomy or ileostomy bags for medical use

An overview on incentives for investors can be found on the website of Kenya Revenue Authority (KRA, <https://www.kra.go.ke>).

<sup>7</sup> United Nations – <https://unctad.org/webflyer/world-investment-report-2022>

<sup>8</sup> Kenya Invest – KenInvest: <http://www.invest.go.ke/>



## Key players in the life science industry

### Pharmaceutical products

Kenya is currently the second-largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region and the third-largest exporter of pharmaceuticals in Africa, exporting an average of USD 63 million worth of products to the COMESA markets<sup>9</sup>. Kenyan manufacturers currently hold 30% of the USD 1.1 billion Kenyan pharmaceutical market. According to the EAC Regional Pharmaceutical Manufacturing Plan, domestic pharmaceutical manufacturers have a strong presence in anti-infective product categories such as cough and cold preparations, antiprotozoals, antiseptics, anti-asthmatics and antibiotics. However, there is also a considerable demand for immunological and cardiovascular therapies that is not covered by domestic manufacturers.<sup>10</sup>

In July 2022 it was announced that country will host a **WHO Emergency Hub for Africa**<sup>11</sup> which will include a Centre of Excellence for the Health Emergency Workforce and warehouses for essential medicines.

### Medical devices

Demand for medical devices remains high, as many healthcare facilities require modernization. In order to support access to modern health care infrastructure for public hospitals, the government has introduced managed equipment services (MES), which ensures that public hospitals have access to modern health infrastructure, equipment and/or services over an agreed period<sup>12</sup>.

### Examples of local pharmaceutical manufactures

According to KENINVEST (<http://www.invest.go.ke>), there are around 35 manufacturers of finished products (secondary production) and a few producers of APIs (primary production) and “fill and finish” companies (tertiary production) in Kenya. Examples include

- **Beta Healthcare International Ltd** (<http://www.betacare.co.ke>) The company has a product portfolio comprising predominantly OTC and branded pharmaceutical products.

<sup>9</sup> IFC: <https://www.ifc.org/wps/wcm/connect/2b7f0aa8-348a-48f5-8367-66176a32450b/2020-Kenya-pharmaceutical-sector-diagnostic-summary.pdf?MOD=AJPERES&CVID=nY88JC>

<sup>10</sup> UNIDO: [https://www.unido.org/sites/default/files/2016-01/EAC\\_Regional\\_Pharmaceutical\\_Manufacturing\\_Plan\\_of\\_Action\\_0.pdf](https://www.unido.org/sites/default/files/2016-01/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action_0.pdf)

<sup>11</sup> WHO: <https://www.afro.who.int/countries/kenya/news/kenya-and-who-launch-bold-initiative-transform-africas-health-emergency-response>

<sup>12</sup> World Bank Group - How Managed Equipment Services in Kenya help the private sector contribute to healthcare ([worldbank.org](http://worldbank.org))

<sup>13</sup> <https://www.devex.com/news/the-significance-of-the-first-who-approved-african-malaria-medicine-103905>

<sup>14</sup> Nation – <https://nation.africa/kenya/business/bangladeshi-firm-to-establish-drugs-plant-in-athi-river-3645832>

<sup>15</sup> Moderna – Moderna to build mRNA vaccine manufacturing facility in Kenya | Reuters

- **Cosmos Pharmaceutical Limited** (<https://cosmos-pharm.com/benefit>) has its headquarters in Nairobi with regional offices across 12 countries in Africa. It manufactures generic medicines covering diabetes, hypertension, infection and pain.
- **Regal Pharmaceuticals** (<https://regalpharmaceuticals.com/production>) is one of the leading manufacturers of quality, essential pharmaceutical products in Eastern and Central Africa. The company operates a state-of-the-art manufacturing facilities designed to produce a wide range of formulations in Nairobi
- **Biodeal Laboratories Ltd** (<http://www.biodealkenya.com>). Situated in Nairobi, Biodeal has 200 employees manufacturing human and veterinary and disinfectants for clinical use.
- **Universal Corporation Limited** (<https://ucl.co.ke>) (UCL) has manufacturing plants close to Nairobi. UCL received a prequalification from WHO for manufacturing of key antimalarial drugs<sup>13</sup>.
- Founded in 2017, **Tasa Pharma** (<https://tasapharma.com>) has established a manufacturing facility. The facility aims to engage in the development, manufacture, and distribution of high-quality sterile pharmaceutical products throughout the East and Central African region.

### Examples of foreign companies include

- **Square Pharmaceuticals** (<https://www.squarepharma.com>) from Bangladesh is building a manufacturing plant in the Athi River EPZ<sup>14</sup> for essential medicine, malarial and diabetes drugs for the Kenyan and East African Community (EAC) markets.

## Medical tourism in Kenya

Private health and wellness facilities are setting Kenya apart as one of the key medical tourist destinations in Africa, a new report shows. Kenya is one of Africa's top beneficiaries of cross-border travel for medical purposes. Public and private medical stakeholders are pushing to set up of a central online information portal to market available specialized services to locals and attract foreign medical tourists.

In recent years, Kenya's largest medical referral facility Kenyatta National Hospital and private institutions have served high profile patients from Uganda, Tanzania, Rwanda, Burundi and the Democratic Republic of Congo (DRC), among others.

Source Kenya takes the lead in medical tourism – Business Daily ([businessdailyafrica.com](http://businessdailyafrica.com))

- **Moderna** (<https://investors.modernatx.com>) recently confirmed its plan to set up a manufacturing facility in Kenya to produce messenger RNA (mRNA) vaccines<sup>15</sup>.
- **GSK Kenya** (<https://www.gsk.com/en-gb/locations/kenya>) operates a warehouse in Nairobi to supply South Africa, West Africa and North Africa. The warehouse has been recently updated to the latest digital standards.
- **Johnson & Johnson** (<https://www.jnj.com/tag/johnson-johnson-kenya>) launched an office in Kenya in 2017. It is involved in R&D and partnerships with local governments, non-governmental organizations (NGOs) and community-based organizations to meet SSA's evolving healthcare needs.
- **Philips Healthcare** (<https://www.philips.co.ke>). The Philips Africa Innovation Hub in was established in Nairobi in March 2014 in order to work on the creation of new inventions and bring them to the market.
- **Terumo BCT** (<https://www.terumobct.com>) opened its first regional office in Nairobi in February 2019. Terumo BCT will work closely with the Kenya National Blood Transfusion Services (KNBTS), which collects, tests, processes and distributes blood and blood products to hospitals in Kenya.

## Health tech

Known as the Silicon Savannah, Kenya's thriving tech scene is home to the most cutting-edge startups on the continent. Its USD 1 billion tech ecosystem offers an attractive space for entrepreneurs, investors and technologists, with established firms such as Facebook, Microsoft, IBM and Intel having found a home in this cradle of innovation<sup>16</sup>. There is large number of digital health start-up companies in Kenya, many of them attracting investments by specialized investors<sup>17</sup>. The interest in digital health in Kenya has been driven by the proliferation of mobile devices, such as mobile phones and tablets, which in tandem with easily accessible mobile payment networks means the digital-enabled public has access to healthcare information at any time and almost anywhere.

## Organizations and associations

- The **Kenya Association of Pharmaceutical Industry** (KAPI, <https://www.kapikenya.org>) is representing biopharmaceutical manufacturers (or their local representatives) that invent and develop medicines and

technologies (e.g., biopharmaceuticals, vaccine healthcare, medical devices, diagnostics) that significantly improve people's lives.

- **Kenya Association of Manufacturers** (KAM, <https://kam.co.ke/about-kam/>) represents the manufacturing and value-add industries in Kenya including pharmaceutical manufacturing companies.
- **Kenya Healthcare Federation** (KHF, <https://khf.co.ke>) is the Health Sector Board of the Kenya Private Sector Alliance (KEPSA). The Federation works with commercial healthcare institutions, professional associations and non-state healthcare firms to support quality and affordable healthcare for all through public-private partnerships.

## Clinical trials

The Pharmacy and Poisons Board (PPB, <https://web.pharmacyboardkenya.org/clinical-trials/>) is the regulatory authority responsible for clinical trial approvals, oversight, and inspections. In addition to obtaining the PPB's permission to conduct research in Kenya, the principal investigator or the head of a research institution must obtain a favorable opinion from the Executive Committee accredited by the **National Commission for Science, Technology, and Innovation** (NACOSTI, <https://www.nacosti.go.ke>) and a NACOSTI research license prior to initiating a study. The objective of NACOSTI is to regulate and assure quality in the science, technology and innovation sector. Several internationally active contract research organizations (CROs) offer services related to clinical trials in Kenya.

Kenya has been among leading African countries participating in international clinical trials, most recently the Oxford COVID-19<sup>18</sup> vaccines with the with the involvement of the **Kenya Medical Research Institute** (KEMRI, <https://www.kemri.go.ke>).

## Infrastructure and logistics

Kenya has five main airports. 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.

Kenya has a stable power supply. 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).

<sup>16</sup> S-GE: <https://www.s-ge.com/en/article/global-opportunities/20213-c6-kenya-tech-hub-fint1>

<sup>17</sup> FT: <https://www.ft.com/content/ff6329f5-463b-44ba-bcf6-4f7277f86bfa>

<sup>18</sup> University of Oxford - <https://www.ox.ac.uk/news/2020-10-30-trials-oxford-coronavirus-vaccine-begin-kenya>

Kenya boasts a vast rail and road network because of sectors such as tea, coffee and cut flowers that continues to attract multinational firms seeking to tap into the eastern and central African market.

Kenya has the third-largest port in Sub-Saharan Africa, providing connectivity to over 80 ports globally.

## Cancer treatment in Kenya

In February 2022 a regional cancer center (<https://cgtrh.go.ke>) opened at the Coast General Teaching and Referral Hospital in the coastal city of Mombasa. This center which will cater for cancer patients in the region and beyond. It is the second public facility of its type in Kenya after the one at the Kenyatta University Teaching, Referral and Research Hospital. The facility is part of the Universal Health Coverage (UHC) pillar of Kenya's development and boasts high-tech equipment and comprehensive cancer care.

## Talent development

Kenya has three strategic organizations supporting science and technology: The **National Commission of Science, Technology, and Innovation** (see section "Clinical trials"), the **National Research Fund** and the **Kenya National Innovation Agency**.

- The **National Research Fund** (NRF, <https://researchfund.go.ke/background>) is established under the Science Technology and Innovation Act. The objective of the NRF is to facilitate research for the advancement of science, technology and innovation.<sup>19</sup>
- The **Kenya National Innovation Agency** (KeNIA, <https://www.innovationagency.go.ke>) was set up to develop and manage the national innovation system. The agency also works with public and private partners to ensure appropriate prioritization, relevant capacity development, innovation recognition and publication of the same.<sup>20</sup>
- In addition, there is also the **Kenya Industrial Research and Development Institute** (KIRD, Homepage | Kenya Industrial Research and Development Institute (KIRDI). Its mandate is to undertake research, development and innovation in industrial and allied technologies and disseminate research findings to support industrial development

<sup>19</sup> National Research Fund of Kenya – <https://researchfund.go.ke/background>

<sup>20</sup> Innovation agency of Kenya – <https://www.innovationagency.go.ke>

<sup>21</sup> University of Nairobi: Our rankings | University of Nairobi ([uonbi.ac.ke](https://uonbi.ac.ke))

## Academic training and research institutions

To date, 32 training institutions have been approved by the Pharmacy and Poisons Board (PPB) in Kenya for medical and pharmaceutical training, comprising seven universities for training pharmacists and 25 diploma colleges for training pharmaceutical technologists. Leading universities and institutes with a focus on medicines and biomedical research include:

- The **University of Nairobi** (<https://www.uonbi.ac.ke>) which is ranked first in Kenya and 11<sup>th</sup> in Africa for Physical Sciences, Life Sciences, Clinical and Health<sup>21</sup>. The **KAVI Institute of Clinical Research** (<https://kav-icr.uonbi.ac.ke/>) is part of the university of Nairobi.
- The **Kenya Medical Research Institute** (KEMRI, <https://www.kemri.go.ke>) in Nairobi is among the leading health research institutes in Africa. The institute has a well-established research infrastructure including a critical mass of biomedical scientists. It also has extensive research links with leading health research organizations in the world.
- The **Center for Biotechnology Research and Development** (CBRD, <https://www.kemri.go.ke>) which is part of KEMRI is mandated to undertake basic and biotechnology-related research on human diseases in Kenya, with the overall goal of contributing to the improvement of human health and welfare.
- In addition, there are several international organizations which conduct research in Kenya. Examples include the **International Livestock Research Institute** (ILRI, <https://www.ilri.org/about-us>) which works to improve food security and reduce poverty in developing countries through research for better and more sustainable use of livestock.

## Contacts

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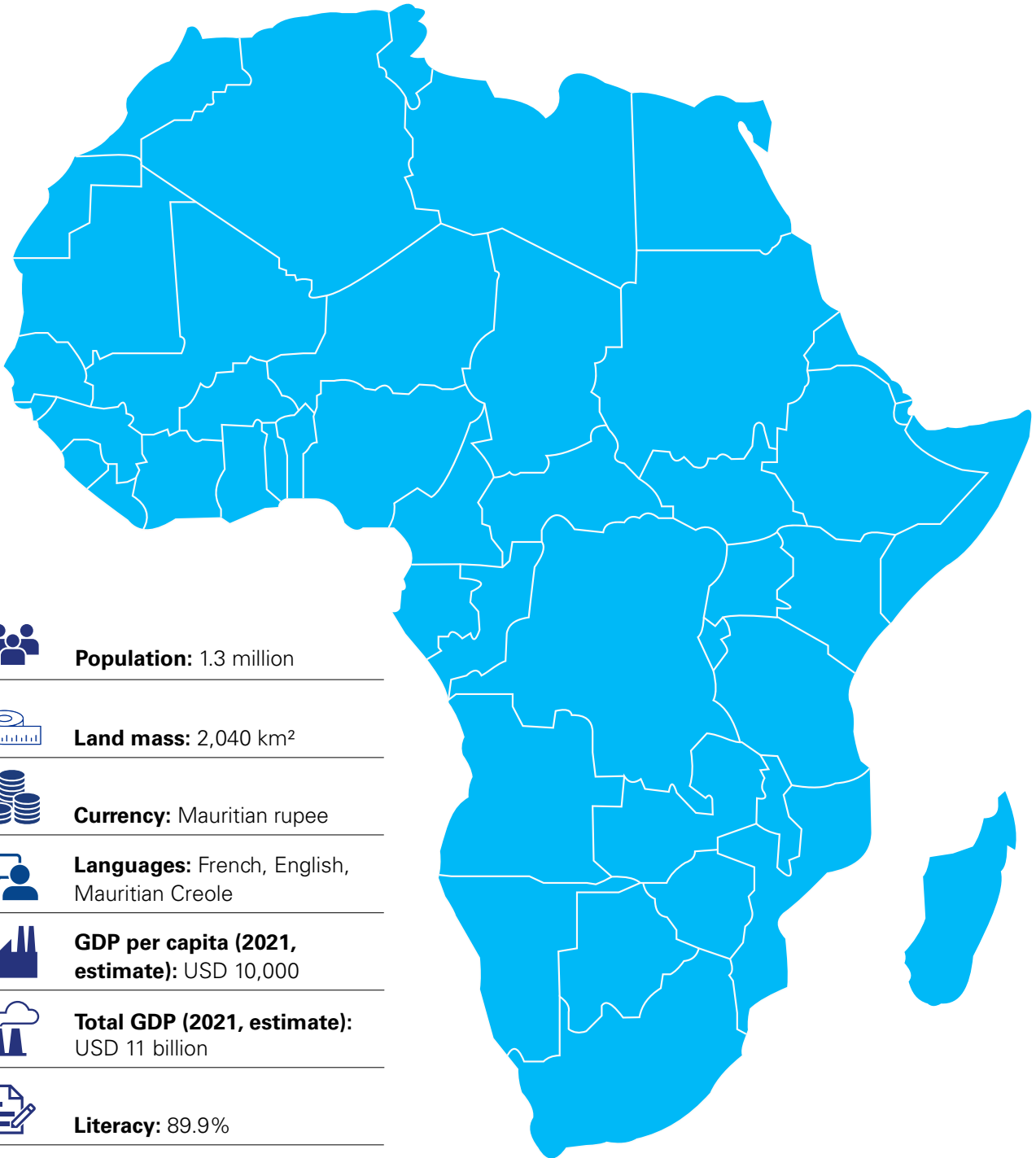
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# Mauritius



**Population:** 1.3 million



**Land mass:** 2,040 km<sup>2</sup>



**Currency:** Mauritian rupee



**Languages:** French, English, Mauritian Creole



**GDP per capita (2021, estimate):** USD 10,000



**Total GDP (2021, estimate):** USD 11 billion



**Literacy:** 89.9%



**Moody's credit rating:** Baa3



**System of government:** Parliamentary republic



An aerial photograph of Mauritius, showing a dense urban area with numerous multi-story buildings in various colors (white, yellow, blue, red). A large harbor is visible on the left, filled with ships and industrial structures like silos. The city extends to the coast, with green fields and a blue ocean in the background under a bright blue sky with scattered white clouds.

**Mauritius is an  
ideal entry point  
for Life Science  
companies into  
Sub-Saharan  
Africa.**



# Snapshot of Mauritius

Mauritius is one of the most developed countries in Africa. As a result of free-market policies and an attractive business regime, Mauritius has one of the highest GDP per capita in Africa. The country is an economic platform for the African continent and has historical investment links with the fast-growing Asian countries. The country strategy is centered around the business as a gateway to Africa and an investment platform positioning for frontier markets in southern and eastern Africa. For life sciences, Africa's high growth and demographic factors create opportunities driven by:

- The urbanization of African countries causing a shift from rural areas to cities, the rise in income for African households and longer life expectancy, leading the population to turn toward more modern medicine spending.
- The change in lifestyle contributing to a substantial increase in non-communicable diseases (NCDs) such as cardiovascular disorders, cancer and diabetes which is expected to account for 60% of illness in Africa in 2020. Mauritius is already setting up specialized infrastructures for cross-border care and medical tourism.
- Preferential agreements at the back of investor protection and a sound capital market ecosystem makes Mauritius ideal for investment into the continent. The Mauritius IFC Africa strategy (International Finance Center Strategy, <https://www.fscmauritius.org/media/67408/highlights-of-blueprint.pdf>) is underpinned by the ability to pool foreign investments into Africa, and is of interest to life sciences private equity funds.
- Historical sectors of the Mauritian economy such as manufacturing (mainly textiles), tourism, financial and business services, information and communication technology, seafood processing, real estate development, energy, and education/training<sup>1</sup> have developed the basic business infrastructures and skills base which can be replicated for life sciences ventures.

## International rankings

- Several international rankings such as the Mo Ibrahim Index of African Governance (<https://iag.online>) rank Mauritius as a favorable business and investment destination in Africa.

- According to the 2022 Index of Economic Freedom (<https://www.heritage.org/index/country/mauritius>), Mauritius's economic freedom score is 70.9, making its economy the 30th freest in the 2022 Index. Mauritius is ranked first among 47 countries in the Sub-Saharan Africa region, and its overall score is above the regional and world averages.
- **Global Innovation Index 2022** ([https://www.wipo.int/global\\_innovation\\_index/en/](https://www.wipo.int/global_innovation_index/en/)): Mauritius maintains its position as a leading magnet for innovation in Africa and is ranked as the 45th most innovative economy globally.

## International connectivity

- Mauritius has signed preferential trade agreements with different blocks of countries which provide duty-free access to Mauritian products.
- In addition, the country's membership of the Indian Ocean Rim, the Common Market for Eastern and Southern Africa (COMESA, <https://www.comesa.int>) and the Southern Africa Development Community (SADC, <https://www.sadc.int>) provides operators from Mauritius with market access to the region.

## Key processes to establish a pharmaceutical manufacturing plant

The Pharmacy Act provides for the main framework for regulating the manufacturing, importation, distribution and sale of pharmaceutical products in Mauritius.

The promoter is required to submit a written application and a copy of the business plan to the Pharmacy Board and the Economic Development Board (EDB, <https://www.edbmauritius.org/newsroom/guidelines-setting-pharmaceutical-manufacturing-unit>). A WHO consultant will evaluate this plan due to the country following the WHO's good manufacturing practices. This will be accompanied by license, which may vary depending on the type of business, i.e., building a factory or a license to manufacture.

<sup>1</sup> <https://www.trade.gov/country-commercial-guides/mauritius-market-overview>

## Tax and other incentives for pharmaceutical manufacturing activities

As a member of SADC and COMESA, exports from Mauritius to members of these organizations benefit from duty-free access, provided the rules of origin are met. The government offers a tax holiday of eight years, 3% corporate tax on profits derived from exports, investment tax credit for investment in high-tech manufacturing, and air and sea freight rebates on exports for new companies involved in the manufacturing of pharmaceuticals.

Special incentives are issued by the Economic Development Board, with a premium investor certificate. Companies are eligible for this certificate for the manufacture of pharmaceuticals and medical devices.

Incentives are also negotiable with the EDB and life sciences operators can avail of the following general incentives:

- 8-year income tax-holiday
- Waiver on building and land use permit fees for construction of pharma manufacturing factories

- 3% corporate tax on profits (after 8 years)
- No import duties on equipment and raw material
- No export duties in Mauritius
- Investment tax credit of 15% per year for three years for investment in high-tech manufacturing equipment
- Full tax credit on the costs of acquisition of patents
- Accelerated depreciation of 50% on machinery, equipment and construction of industrial premises dedicated to manufacturing activities
- VAT on raw materials is payable at customs clearance but reimbursable on export
- Exemption registration duty on the purchase/lease of land for the construction of infrastructure
- Exemption of VAT on construction of private hospitals/clinics, residential care homes/nursing homes
- VAT exemption on medical, surgical and dental equipment
- No customs duty on selected equipment, machinery, and furniture
- Medical, hospital and dental services are zero-rated for VAT
- 5% allowance on capital expenditure incurred on construction/extension of clinic
- Free repatriation of profits, dividends and capital
- No capital gains tax
- 100% foreign ownership allowed

<sup>2</sup> <https://www.trade.gov/country-commercial-guides/mauritius-pharmaceuticals>



## Key players in the life sciences industry

### Key market insights

Mauritius depends on the importation of pharmaceutical products for public and private healthcare. In 2019, the market value of imported pharmaceutical products was estimated to be MUR 5 billion (USD 119 million) or 20 percent of the total healthcare expenditure.<sup>2</sup>

The biotech industry in Mauritius is one of the sectors with the most favorable prospects. Over the last few years, this sector has been expanding due to favorable governmental measures and incentives that have been put in place through the introduction of the 2019 Industrial Property Bill. Many organizations have been created with the aim of improving the healthcare sector, allowing these organizations to supply services in the areas of clinical trials, breeding of live samples for export, and manufacture of biofuels, among others. The country currently has five contract research organizations in charge of clinical trials, four in breeding for contract research and six analytical laboratories/research laboratories.

### Case studies and major achievements supporting the above are:

- **Aspen Global** (<https://www.aspengl.com>) was incorporated in February 2008 in Mauritius and is one of Mauritius's largest companies with a turnover exceeding 40 billion Mauritius Rupees. Aspen Global forms part of a group with 60 subsidiaries worldwide. Aspen has used Mauritius as a base for the establishment of a global distribution network where the commercial, logistical and administrative infrastructure to roll out the Commercial Pharmaceuticals portfolio to more than 100 markets worldwide are managed from Mauritius.
- Mauritius has emerged as one of the key suppliers of primates for research by world class research laboratories. To date the export of primates is among the top 10 exports of Mauritius. Since 2017 (with the introduction of the Animal Welfare (Experiment on Animals) Act there are new opportunities for companies involved in breeding to have access to the full chain of pharmaceutical research. The Act now enables these companies to collaborate with biotech companies and enter the pre-clinical research fields.
- **Natec Medical Ltd** (<https://www.natec-medical.com>) is a home grown integrated design, development and manufacturing company specialized in percutaneous interventional medical devices (PIDs) for the global market. They design and manufacture angioplasty balloon catheters for interventions in cardiology,

radiology, gastroenterology and urology. Its current portfolio covers wide range of PTCA & PTA balloon catheters, stent delivery systems as well as crimping services, EtO sterilization services and microbiological analysis services. Natec is currently setting up the AVA Technopark, a pioneering technological park engaged in medical research and the creation and design of advanced medical devices.

Mauritius is surrounded by emerging markets with low life sciences activity penetration. The advanced manufacturing setup in South Africa and the southern African biosphere gives Mauritius the proximity with key suppliers of phytotherapy, cosmetic essence and primate supplies. This offers a good combination for pre-clinical research and vaccine development frameworks.

## Infrastructure and logistics

As part of its commitment to develop the pharmaceutical industry, the Mauritius government has earmarked an area of 66.5 acres of land with direct motorway access to the airport to develop a pharmaceutical and life sciences park (AVA Technopark). The proposed activities will aim to promote the manufacture of pharmaceutical products, manufacture of medical devices, instruments and products, cosmetics, R&D and research laboratories and support services related to the development of the pharmaceutical industry.

### Freeport warehousing and value-add services framework and infrastructures

Strategically located, Mauritius Freeport was created in 1992 with the main objective of developing Mauritius into a competitive logistics and distribution hub for international trades. Over the years, the freeport has evolved into a thriving business platform and is now home to global operators. This success can be attributed to the high-quality services offered by the freeport stakeholders but also the specialized infrastructures that have been developed. The freeport infrastructures currently comprise of warehousing facilities, processing units, cold rooms and offices conforming to rigorous international norms and standards.

According to the Economic Development Bank<sup>3</sup>, the top freeport trading partners at import in 2021 were Taiwan, China, India, Singapore and South Africa whereas South Africa, Madagascar, Reunion, United States and Taiwan were the top freeport trading partners at export.

### Air connectivity

Mauritius is served by more than 20 airlines, connecting over 150 destinations world-wide. Mauritius has direct service to 9 of the top 15 airport hubs in the world. This

<sup>3</sup> Economic Development Bank – <https://www.edbmauritius.org/why-mauritius>

<sup>4</sup> Economic Development Bank – Lifesciences | EDB MAURITIUS



includes Paris, London, Singapore, Dubai, Johannesburg, Nairobi, New Delhi, Mumbai and Perth.

### Port connectivity

Mauritius is developing an island container terminal to cater for container traffic beyond 2025. The government is investing MUR 47 billion (USD 1.3 billion) for the development of the blue economy and the transformation of the Port Louis Harbor into a regional maritime hub.

### Telecommunications

Mauritius is currently connected to two undersea cables, namely: **South Africa Far East (SAFE)** and **Lower Indian Ocean Network (LION)/LION2** cables for the provision of international internet capacity. **Indianoceanic Submarine System (METISS)** connecting Mauritius, Reunion Island, Madagascar and South Africa. In addition, the Central Electricity Board has implemented a second national fiber optic cable backbone in Mauritius through **Fibrenet**.

## Clinical trials

### Genetic and demographic features which favor clinical trials

Possessing unique genetic and demographic attributes, the Mauritian population displays ideal features for clinical research and trials. Particularly, the cosmetic research field benefits immensely from the different lifestyle, multi-ethnicity and skin diversity of the population for the purpose of their research. Besides the genetic diversity, the main chronic diseases affecting the Mauritian population reflect the areas that are gaining the attention of big pharmaceutical firms, such as cardiovascular disease, cancer and diabetes. These are the also conditions that are currently increasing at an exponential rate in other developing African countries. Situated in the southern hemisphere, Mauritius has been able to develop a whole line of research in photobiology and conduct studies on tanning, melanoma and cancer. So far, more than 1000<sup>4</sup> trials have been carried out in the area of cosmetics and pharmaceuticals.

The Government of Mauritius has introduced the Clinical Trials Act, adopted by the National Assembly on 19 April 2011, to provide the legal framework to conduct clinical trials. The establishment of this act resulted in the island having many developments in the life sciences space, especially pharmaceutical and cosmetic research development. Three main committees act as regulatory bodies: the Clinical Research Regulatory Committee, the Ethics Committee, and the Pharmacovigilance Committee.

The country serves as a medical hub for several research contract research organizations which are well positioned in the country due to the availability of skilled professionals in the health care sector and appropriate regulations. For details see EDB, [https://www.edbmauritius.org/sites/default/files/2021-09/CLINICAL%20TRIALS%20GUIDELINES\\_0.pdf](https://www.edbmauritius.org/sites/default/files/2021-09/CLINICAL%20TRIALS%20GUIDELINES_0.pdf).

## Talent development

Mauritius leads the regional group ranking of the Global Talent Competitiveness Index 2021 (<https://www.insead.edu/faculty-research/research/gtci>). The GTCI measures the attractiveness of countries for highly skilled workforce and their families. Mauritius is becoming a particularly interesting mobile workforce. In view of developing Mauritius as an innovation-driven economy, the government of Mauritius aims at positioning Mauritius as the leading education hub for the region. Mauritius is today a significant provider of quality education. Building upon this reputation, Mauritius is attracting an increasing number of local and international students. Since 2007, the number of international students has grown from 528 to 3,300 in December 2020. The students come from more than 70 different countries, mainly India, Nigeria, South Africa, Madagascar, France, Uganda, Kenya and Tanzania amongst others.

## Organizations and associations

**Business Mauritius** (<https://www.businessmauritius.org>) represents over 1200 local businesses as an independent association.

The **Economic Development Board** (EDB, <https://www.edbmauritius.org/>) provides information to investors planning to set up operations in Mauritius.

## Contacts

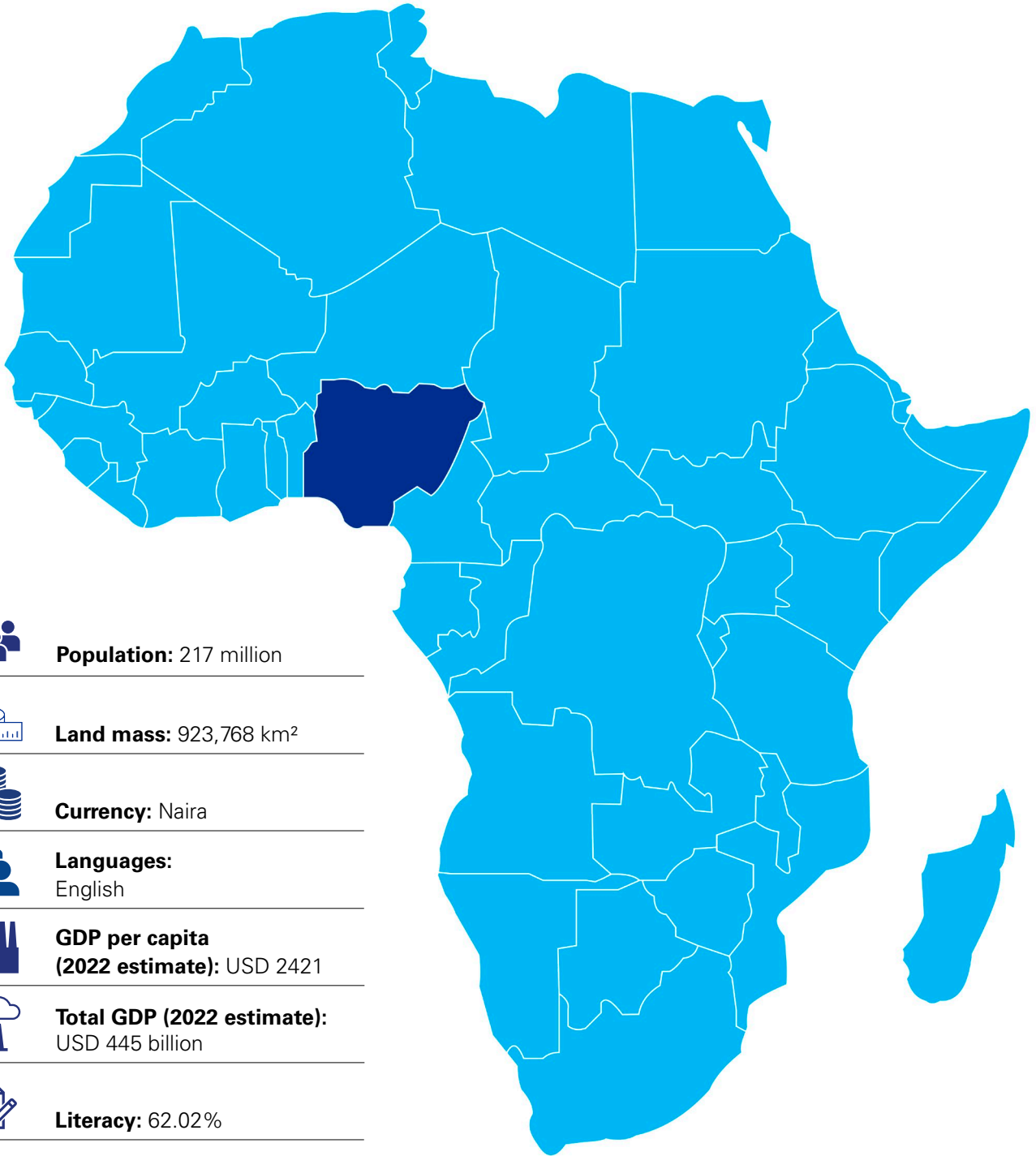
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<https://home.kpmg/mu/en/home.html>

# Nigeria



**Population:** 217 million



**Land mass:** 923,768 km<sup>2</sup>



**Currency:** Naira



**Languages:**  
English



**GDP per capita  
(2022 estimate):** USD 2421



**Total GDP (2022 estimate):**  
USD 445 billion



**Literacy:** 62.02%



**Moody's credit rating:** B3



**System of government:**  
Presidential



An aerial night photograph of a coastal city. A multi-lane highway runs along the waterfront, with light trails from vehicles. To the left is a harbor with a large offshore oil rig. The city skyline is visible in the background with various illuminated buildings. In the foreground, there are parking lots filled with cars and a large industrial or commercial building with a corrugated metal roof.

**With over 200  
million inhabitants,  
Nigeria is the most  
populous country  
in Africa.**



# Snapshot of Nigeria

Nigeria is home to about 217 million people and is the largest country by population on the African continent, with a population expected to rise to over 400 million by 2050.<sup>1</sup> Nigeria is Africa's largest economy in nominal terms with an estimated GDP of USD 440 billion in 2021. The economy grew at 3.4% in 2021, driven mainly by high growth in service-based sub-and non-oil industrial sectors, and further recorded a 3.54% real GDP growth in Q2 2022.

The country is one of the more developed African-Anglophone pharmaceutical markets and has been hailed as the next frontier for pharma after South Africa and the hotspots of Northern Africa.

The country imported pharmaceuticals products worth USD 3.1 billion in 2021, representing 84% of pharmaceutical sales in the same period. Nigeria's key pharmaceutical import partners include India, China and the US. Imports remain key to meeting growing local demand for medicines. Over the years, investment in the healthcare sector has significantly improved, as private investors attempt to close local production gaps.

## International rankings

- In March 2022, World Health Organization (WHO) announced that Nigeria's medical products regulatory agency, the National Agency for Food and Drug Administration Control (NAFDAC, <https://www.nafdac.gov.ng>), has been certified as an ML3 Regulatory Authority, meaning the agency has met WHO and other international standards in regulating medical products in an efficient, effective and in a transparent manner<sup>2</sup>.
- Lagos is the biggest metropolitan area in Africa and has made a name for itself as a tech hub, rapidly advancing towards a 24-hour economy and generating 10% of Nigeria's total GDP. When it comes to attractiveness for startups, Lagos leads the ranking of African cities, according to the World Economic Forum (WEF, <https://www.weforum.org>)<sup>3</sup>.

<sup>1</sup> UN Sustainable Development: Microsoft Word – 21June\_FINAL PRESS RELEASE\_WPP17

<sup>2</sup> WHO: Egypt and Nigeria medicines regulators achieve high maturity level in WHO classification and WHO launches list of regulatory authorities that meet international standards

<sup>3</sup> Weforum: <https://www.weforum.org/platforms/centre-for-the-new-economy-and-society/articles/lagos-africa-startup-capital>

<sup>4</sup> Brookings: <https://www.brookings.edu/blog/africa-in-focus/2021/09/22/quantifying-the-impact-on-nigeria-of-the-african-continental-free-trade-area/>

<sup>5</sup> National centre for biotechnology information: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7375215/>

## International Connectivity

- Nigeria is a member of the African Continental Free Trade Area (Home – AfCFTA ([au-afcfta.org](http://au-afcfta.org)). Nigeria – the largest economy in Africa – signed the AfCFTA in 2019, becoming the 34th member of the trading bloc. The agreement promises zero tariff on most goods traded and will therefore create new market for local drug manufacturers in Nigeria and foreign drug manufacturers seeking to use Nigeria as a manufacturing hub to serve the region<sup>4</sup>.
- Nigeria has access to the US markets through a unilateral commitment by the US to reduce tariffs under the African Growth and Opportunity Act (AGOA <https://nepc.gov.ng/trade-facilitation/trade-agreements>).
- Nigeria is part of ECOWAS Trade Liberalization Scheme (ETLS) a trade instrument designed by the Economic Community of West African States (ECOWAS, <https://nepc.gov.ng/blog/trade-agreement/ecowas>).

## Key processes to establish a pharmaceutical manufacturing plant

The Nigerian government is determined to make the country self-sufficient in pharmaceutical manufacture. The **National Agency for Food and Drug Administration and Control (NAFDAC)** (<https://www.nafdac.gov.ng>) has a "Five plus Five Years Validity" policy ensuring that newly registered pharmaceutical products have a maximum of 10 years to migrate to local production. The transition can be made through a partnership with a Nigerian company or by setting up a local manufacturing plant in Nigeria for finished pharmaceutical products, active pharmaceutical ingredients, non-active pharmaceutical ingredients or packaging materials, among other things. Failing to do so would cancel the product's registration, preventing its importation and distribution in Nigeria. Migration to local manufacturing is however limited to those products that local manufacturers have the capacity to produce or to those that the new partnership would enhance the capacity to manufacture<sup>5</sup>.

The **NAFDAC** (<https://www.nafdac.gov.ng>) is the main regulatory body for the life sciences industry. The **National Drug Policy** is aimed at strengthening the nation's health system and the delivery of medicines, vaccines and other health technologies and supplies. This includes local drug production, patronage of locally produced drugs, etc.

The country's **pricing regime** is controlled by market forces with tariffs, taxes and distribution markups accounting for a significant portion of the price.

A requirement under the **National Drug Distribution Guidelines** is that manufacturers route their medicines to state and mega distribution centers.

Medical devices have to be registered according to the provisions of Act Cap F33 LFN 2004 before they can be manufactured, imported, exported, advertised, sold or distributed in Nigeria.

## Tax and other incentives for pharmaceutical manufacturing activities

Nigeria has introduced various initiatives to encourage activities in the healthcare sector. Through its National Development Plan (NDP), the federal government of Nigeria is leveraging technology and boosting private partnerships in the health sector over the next five years with a targeted investment of NGN 1.65 trillion (ca. USD 3.86 billion). The CBN has disbursed so far around USD 310mn for the healthcare sector under its Healthcare Sector Intervention Facility (HSIF).

A raft of monetary policy initiatives has been implemented by the Central Bank of Nigeria (CBN) to achieve growth potential in the sector, to facilitate credit and encourage research and development activities. This could provide potential upsides for more private sector driven projects particularly in life sciences.

The CBN recently introduced the Healthcare Sector Research and Development Intervention Scheme (HSRDIS)<sup>6</sup> to help strengthen the public healthcare system with innovative financing for research and development in new and improved drugs, vaccines and diagnostics of infectious diseases. The HSRDIS fulfills its mandate by providing grants to biotechnological and pharmaceutical companies, institutions, researchers and research institutes. Other objectives of HSRDIS include boosting domestic manufacturing of validated drugs and improving the capacity of the biotechnological and pharmaceutical companies.

Pharmaceutical manufacturers can apply for **pioneer status**. Pioneer status is a fiscal incentive provided under Industrial Development and administered by the **Nigerian Investment Promotion Commission (NIPC)**, <https://www.nipc.gov.ng/>. The incentive entitles eligible companies to income tax holidays for up to five years – three years in the first instance, renewable for an additional maximum period of two years. In addition to

the income tax holiday, pioneer companies enjoy other benefits, such as withholding tax exemption for dividends paid out of pioneer profits.<sup>7</sup>

The Nigerian legal system is modeled after English Common Law, modified by statutes to meet local demands and conditions. Nigerian laws in areas such as patents, trademarks, copyrights and business associations considerably reflect corresponding British statutes in these areas as at the dates of their first enactment<sup>8</sup>.

## Key players in the life sciences industry

### Pharmaceuticals

Key players in the Nigerian pharmaceutical industry include: Emzor Pharmaceutical Products, May & Baker Nigeria Plc, Mopson Pharmaceutical Limited, Swiss Pharma Nigeria Limited, Fidson Healthcare Plc, Chemiron International Limited, GlaxoSmithKline Plc, Neros Pharmaceutical Limited and Zolon Healthcare Limited.

A number of agreements are in place between international life sciences firms and local producers. These will provide opportunities for domestic firms to expand their manufacturing capacities. For example, Emzor pharmaceuticals, a leading manufacturer of medicines in Nigeria, signed an agreement in 2021 with India's Mangalam Drugs & Organics Limited, to locally manufacture and distribute Active Pharmaceutical Ingredients (APIs) for the treatment and prevention of malaria<sup>9</sup>.

### Biotechnology

Nigeria's biotech Industry is at a nascent stage. A recent example of a Nigeria/US-based biotech company includes **54Gene** (<https://54gene.com/>), a company founded as a healthcare startup centered on improving treatment outcomes through genetic research and development. 54Gene closed a USD 15 million Series A funding round in April 2020, and in September 2021 secured another USD 25 million in a Series B round, bringing the company's total investment to over USD 45 million as at 2021. The company has unveiled the first genome sequencing lab in Nigeria alongside an American biotech company.

### Medical technology

Nigeria's medical device production is at an early stage, with output of less than USD 5 million in 2021. Production is focused on consumables and basic medical devices.

<sup>6</sup> This day: <https://www.thisdaylive.com/index.php/2020/09/30/cbn-amends-healthcare-sector-intervention-scheme/>

<sup>7</sup> KPMG: <https://home.kpmg/ng/en/home/insights/2018/11/FG-issues-Official-Gazette-of-approved-pioneer-industries-and-products.html>

<sup>8</sup> KPMG: [investment-in-nigeria-guide-8th-edition-may-2021.pdf](https://www.kpmg.com/~/media/assets/2021/05/investment-in-nigeria-guide-8th-edition-may-2021.pdf) (assets.kpmg)

<sup>9</sup> Health Care Africa: <https://www.healthcareafrica.info/nigerias-emzor-mangalam-ink-deal-to-manufacture-apis-in-africa/>



Key local players in the Nigeria's medical devices include Jubilee Syringe Manufacturing and Medical Plastics Limited. Multinational companies involved include GE Healthcare, Johnson & Johnson, etc.

## Health tech

Nigeria is adopting telemedicine to increase access to healthcare. In 2008 the **National Space Research and Development Agency** (NASRDA, <https://africanews.space/nigerian-space-agency-launches-telemedicine-facility-to-support-covid-19-testing-in-nigeria>) and the Federal Ministry of Health partnered to introduce telemedicine programs in teaching hospitals and medical centers across the country. Nigeria's digital advantage in terms of rising telecommunication subscriber base (over 150 million) and mobile broadband infrastructure may provide succor to delivering health care services affordably and with a wider reach, particularly to remote areas.

According to a report by the **Financial Times**, of the USD 209 million raised by African health technology companies in 2021, around a fifth went to Nigerian firms, putting the country second only to South Africa<sup>10</sup>. According to research group **Tracxn**, there are ca. 180 health tech companies developing products in Nigeria<sup>11</sup>.

## Infrastructure and logistics

The growth of the digital economy is one of the Nigerian government's focus areas and the country already has one of the largest ICT markets in Africa. Digitalization is set to continue to grow and develop in 2022, supported by the waiver of fees for laying fiber-optic cables and various government regulations. These investments will be most crucial in achieving the country's goal of fostering a buoyant digital economy<sup>12</sup>.

There is a number of Technology Parks located in Nigeria. One example is the Abuja Science and Technology Park (STP, <http://abujatechnologyvillage.com>). The STP is poised to become Africa's preferred destination for technology

research, incubation, development and commercialization across four focus sectors (information and communication technology (ICT), biotechnology, minerals technology and energy technology).

## Talent development

There is a large pool of talented and ambitious graduates available in Nigeria. Many graduates from Nigerian universities find it hard to find a job in Nigeria, however<sup>13</sup>. High unemployment – one in three young people are without work – and comparatively poor living conditions mean many of Nigeria's brightest would rather take their chances abroad than return home. This opens up attractive recruiting opportunities for companies looking to hire qualified graduates in Nigeria.

An important institution is the **National Institute for Pharmaceutical Research and Development** (NIPRD, <https://chasebalo1.wixsite.com/niprd>). **Afreximbank** has awarded USD 400,000 in 2021 in grant funding to the NIPRD for the establishment of an API plant<sup>14</sup>.

**African Development Bank** Group's USD 3.56 billion grant to build Africa's pharmaceutical industry over the next 10 years is expected to increase the number of drug manufacturers in the continent, especially for key countries like Nigeria<sup>15</sup>.

## Organizations and associations

The **National Biotechnology Development Agency** (NABDA, <https://nabda.gov.ng>) is charged with the promotion, coordination and setting of research and development priority for biotechnology in Nigeria. The NABDA seeks to design programs that are in line with international standards while simultaneously developing local technological contents. The Agency has 34 bioresource centers across the country where services such as environmental biotechnology and bio conservation, genetics, genomics bioinformatics, bio entrepreneurship and extension services, agricultural biotechnology and medical biotechnology are carried out.

The **Nigerian Investment Promotion Commission** (NIPC, <https://www.nipc.gov.ng>) is responsible for encouraging, promoting and coordinating investments in Nigeria. The agency provides services for the granting of business entry permits, licenses, authorizations and incentives.

The **National Agency for Food and Drug Administration and Control** (NAFDAC, <https://www.nafdac.gov.ng>), the WHO and the Pharmaceutical Society of Nigeria are

<sup>10</sup> Financial times: <https://www.ft.com/content/da2fdc82-fd3d-4628-a9dd-b83bb8a766d3>

<sup>11</sup> Tracxn: <https://tracxn.com/explore/HealthTech-Startups-in-Lagos>

<sup>12</sup> KPMG: <https://home.kpmg/content/dam/kpmg/ng/pdf/2022-macroeconomic-review.pdf>

<sup>13</sup> BBC: <https://www.bbc.com/news/world-africa-58319976>

<sup>14</sup> African Export-Import Bank: <https://www.afreximbank.com/afreximbank-awards-us400000-grant-to-nigerias-niprd-to-boost-local-production-of-active-pharmaceutical-ingredients/>

<sup>15</sup> African Development Bank: <https://www.afdb.org/en/news-and-events/press-releases/african-development-bank-group-signs-memorandum-understanding-ecowas-356-million-grant-develop-west-africa-pharmaceutical-industry-50572>

collaborating to raise the standards of medicines produced locally and also supporting local producers to attain WHO pre-qualification status.

**Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria** (PMG-MAN, <https://pmgman.com>), a subsector of the Manufacturers Association of Nigeria (MAN), represents all the manufacturers of pharmaceuticals and allied products in Nigeria, which collectively play a key role in ensuring that Nigerians have timely access to affordable, safe and high-quality medicines.

The **Pharmaceutical Society of Nigeria** (PSN <https://www.psnnational.org/index.php/about-us/aims-and-objectives>) is the umbrella association advocating for the improvement and welfare of all groups in the Nigerian pharmaceutical sector.

The **Nigerian Economic Summit Group** (NESGROUP, <https://nesgroup.org>) is the leading private sector association representing key economic sectors. NESGROUP launched the Nigerian Economic Summit (NES) and sustained it as a platform for bringing together private sector leaders and senior public sector officials to discuss and dialogue on the future of the Nigerian Economy.

The **Lagos Chamber of Commerce and Industry** (LCCI) is the largest regional Chamber of Commerce (Lagos Chamber of Commerce & Industry – Giving Your Business A Voice).

## Contacts

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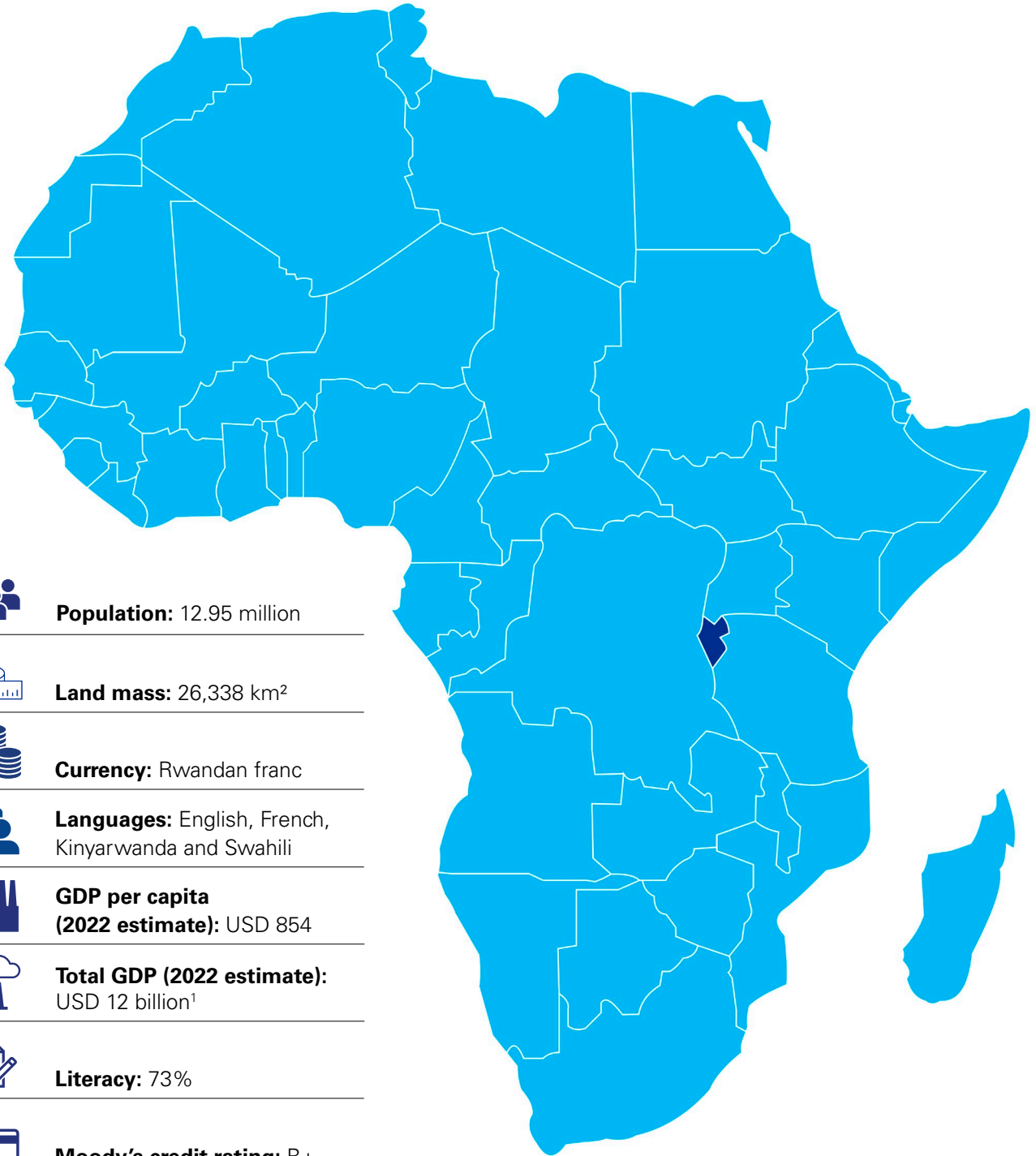
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# Rwanda



**Population:** 12.95 million



**Land mass:** 26,338 km<sup>2</sup>



**Currency:** Rwandan franc



**Languages:** English, French, Kinyarwanda and Swahili



**GDP per capita (2022 estimate):** USD 854



**Total GDP (2022 estimate):** USD 12 billion<sup>1</sup>



**Literacy:** 73%



**Moody's credit rating:** B+



**System of government:** Presidential

<sup>1</sup> World bank: <https://data.worldbank.org/indicator/NY.GDP.MKTP.KD?end=2021&locations=RW&start=2000>



**Rwanda was  
selected to host the  
Headquarters of  
African Medicines  
Agency.**



# Snapshot of Rwanda

Rwanda is one of the fastest growing economies in Africa with average growth of more than 7% in the past decade and GDP growth of 10.9% in 2021<sup>2</sup>. With a young and educated population – 70% of the population is under 30 – the country offers attractive conditions for doing business, both in terms of market size and finding qualified talents. In July 2022 the Executive Council of the African Union Council chose Rwanda to host the headquarters of the African Medicines Agency (AMA)<sup>3</sup>. Approximately 80.0%<sup>4</sup> of pharmaceuticals consumed in the country are sourced internationally, with over half originating from India and Belgium. Looking ahead, local manufacturers' small-scale and basic capabilities mean the country will continue to rely on imports for its pharmaceutical needs. Rwanda has worked well to mitigate the effect of Covid-19 on the country's drug supply; however, efforts are still needed to invest in local pharmaceutical production to minimize import expenses in the country.

## International rankings

- Rwanda is ranked one of most business-friendly countries on the African continent according to the Ibrahim Index of African Governance (IIAG, <https://mo.ibrahim.foundation/iiag>).
- Rwanda leads globally in the number of female parliamentarians and female cabinet members in the world according to the latest report by the Inter-Parliamentary Union (IPU, <https://www.ipu.org>)
- Rwanda was ranked 52nd out of 180 countries and cited as one of sub-Saharan Africa's three least corrupt nations in Transparency International's 2021 Corruption Perceptions Index (<https://www.transparency.org>)

## International connectivity

Rwanda has access to African and global markets through a network robust free trade agreements and other treaties, namely:

- Common Market for Eastern and Southern Africa (COMESA <https://www.comesa.int>)

- East African Community (EAC, <https://www.eac.int>)
- Tripartite Free Trade Area Agreement (COMESA EAC SADC, <https://www.eac.int>)
- African Continental Free Trade Area (AfCFTA, <https://au-afcfta.org>)
- Cotonou Agreement established with the EU ([https://international-partnerships.ec.europa.eu/policies/european-development-policy/acp-eu-partnership\\_en](https://international-partnerships.ec.europa.eu/policies/european-development-policy/acp-eu-partnership_en))
- Rwanda also has preferential access to several international markets through the WTO's special and differential treatment provisions. This has included access to the US markets through a unilateral commitment by the US to reduce tariffs under the African Growth and Opportunity Act (AGOA, <https://www.cbp.gov>).

## Key processes to establish a pharmaceutical manufacturing plant

Companies planning to set up a manufacturing plant for pharmaceutical products in Rwanda must adhere to the following process:

- Submission of a letter of intent to manufacture addressed to Rwanda Food and Drugs Authority (RFDA, <https://www.rwandafda.gov.rw/home>).
- Business registration as foreign investor with the Rwanda Development Board (RDB, <https://rdb.rw/e-services>). The registration is fully digitalized. A foreign investor is an individual who is not a Rwandan national or a resident of a Partner State of the East African Community or of a member State of the Common Market for Eastern and Southern Africa or of a member. The registration enables the investor to apply for an investment certificate.
- Completed application for manufacturer of medical products with RFDA.
- Completed environmental impact assessment report with RDB.

<sup>2</sup> World bank: <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?end=2021&locations=RW&start=2000>

<sup>3</sup> Africa News: <https://www.africanews.com/2022/07/18/au-selects-rwanda-to-host-hq-of-new-african-medicines-agency/>

<sup>4</sup> Fitch Solutions: <https://www.fitchsolutions.com/pharma-healthcare/rwandas-pharmaceutical-healthcare-markets-post-modest-growth-over-medium-term-24-05-2021>



## Tax and other incentives for manufacturing activities

The government has launched a “Made in Rwanda” policy to foster manufacturing in Rwanda. To attract investments, the government has created several special economic zones and has introduced various fiscal and non-fiscal incentives for investors.

Fiscal incentives include:

- Duty-free imports of machinery and inputs via EAC (<https://www.eac.int/>) customs management
- Seven-year corporate income tax (CIT) holiday for investors investing more than USD 50 million
- 15% preferential corporate income tax for investors exporting at least 50% of their production outside of EAC or for priority sectors
- 0% corporate income tax if regional HQ is in Rwanda
- Accelerated depreciation of 50% for the first year
- Exemption of VAT on imported medical equipment
- Capital gains for sale or transfer of shares are tax exempt
- Non-financial incentives include quick online registration for company incorporation and investment certificate (six hours to register a business); assistance with tax related services and exemptions, assistance to access utilities (water, electricity), assistance with obtaining visas and work permits among others; foreign companies investing at least USD 250,000 are allowed to recruit three foreigners without a labor test

Rwanda is open for foreign direct investments (FDIs) and there is no restriction on foreign ownership or on capital flows.

An overview of investment regulations and investment opportunities can be found on the website of the **Rwanda Development Board** (RDB, <https://rdb.rw>). It offers a one-stop center for investors with a dedicated investment acceleration and aftercare team.

### Incentives for local manufacturing

Procurement by the government of Rwanda equals 12% of total GDP. To promote local production over imports, the “Made in Rwanda” policy allows for a benefit in public procurements provided that more than 30% of total value of the final product is added in Rwanda. Bids meeting this

criterion get a 15% local preference over other bids. When the domestic value addition is significantly high (30% value addition), import duties are 0% for raw materials and machinery and the products are also VAT exempted. This applies to imports from all countries outside the East-African Custom Union.

## Key players in the life sciences industry

The special economic zone of Kigali (KSEZ, <https://www.pez.rw>), has become the center for foreign companies, planning to start manufacturing in Rwanda. Examples of companies which have established a presence in the KSEZ are set out below:

**Pharmalab Ltd** (PharmaLab Ltd | EA Health) is a manufacturer of medical and laboratory equipment as well as as well as disposable medical and laboratory consumables. The company specializes in manufacturing of different types of blood tubes collections, stool and urine containers, and a range of medical consumables while also being a distributor of human diagnostics.

Moroccan company **Cooper Pharma East Africa** (<https://cooperpharma.ma>) operates a 20,000m<sup>2</sup> manufacturing plant for pharmaceutical products such as intravenous (IV) fluids at KSEZ with medium-term plans to start producing antibiotics.

Bangladeshi **Apex Biotech** ([www.apexbiotech.net](http://www.apexbiotech.net)) opened a manufacturing plant in KSEZ in September 2021. The plant is licensed under the Rwanda FDA to manufacture 34<sup>7</sup> various type of drugs, which will lead to a substantial reduction of imports of medication into Rwanda.

In June 2022, German company **BioNTech** (<https://www.biontech.com/>) began construction on the first local mRNA vaccine manufacturing facility in Africa in the KSEZ. The delivery of first container of manufacturing modules is planned for the end of 2022<sup>8</sup>.

<sup>6</sup> Leaf Pharmaceutical: <https://www.leafpharmaceuticals.com/leaf-pharmaceuticals-newsroom>

<sup>7</sup> New times : Five things you should know about Rwanda's first pharmaceutical plant | The New Times | Rwanda

<sup>8</sup> Investors Biontech- <https://investors.biontech.de/news-releases/news-release-details/biontech-starts-construction-first-mrna-vaccine-manufacturing/>



## Health tech

According to the World Economic Forum (WEF, [www.weforum.org](https://www.weforum.org)), Rwanda is making strides to become an innovation hotspot in Africa and pushing forward with digital development. In November 2021, the Rwanda Innovation Fund (RIF)<sup>11</sup> was launched to support innovative companies through a public-private partnership<sup>12</sup>. Early in 2022 the **Norrskén Foundation** (<https://www.norrskén.org/eastafrica>), a Swedish-based investment fund, opened the “Norrskén House” in Kigali aimed at providing a collaborative environment where education, innovation and entrepreneurship join to generate scalable growth and development.

Examples of digital healthcare companies with activities in Rwanda include

- **Zipline** ([flyzipline.com](https://flyzipline.com)) – The company first started its operations for Africa in Rwanda in 2016 offering quick, efficient, and equitable distribution of blood across the country, while also controlling inventory levels and keeping spoilage low. The operation uses fixed-wing drones to deliver lifesaving medical supplies by drones.
- **Babyl** (<https://www.babyl.rw>), a digital healthcare provider offering online medical consultancy, entered into a 10-year partnership with the government of Rwanda in March 2020 to build Africa’s first universal primary care service, using a digital-first approach.

## Infrastructure and logistics

Rwanda’s envisions becoming the main logistic hub for Eastern and Central Africa due to its geographical location. The government is heavily investing in transport infrastructure. Recently, several main roads have been upgraded such as the Huye-Kitabi Road and the Kagitumba-Gabiro Road.

### Air transport

Flight transport has become an essential driver for the economic, social, and cultural development of Rwanda as a land-locked country. Through national carrier **Rwandair** (<https://www.rwandair.com/>) there a numerous daily direct connection to capital cities in Europe, Africa, North

America, the Middle East and Asia. Beside Kigali International Airport, construction is underway for New Bugesera International Airport (NBIA) in partnership with Qatar Airways.<sup>13</sup>

## Talent development

- The **University of Rwanda** (UR, <https://ur.ac.rw>) is the leading university in the country. It has eight campuses across the country. Four of them offer courses in medicine, pharmacy, sciences or veterinary studies.
- The private institution **University of Global Health Equity** (<https://ughe.org>), a medical school based in rural Butaro, trains global health professionals. The university was opened through the partnership of the Cummings Foundation (Rwanda | Cummings Foundation) and the Bill & Melinda Gates Foundation (Bill & Melinda Gates Foundation | Bill & Melinda Gates Foundation) in 2019. The institution has also partnered with various institutions such as Harvard School of Public Health and the University of Rwanda. It also partners with other organizations to offer various academic programs.
- The BioNTech (<https://www.biontech.com>) mRNA facility in Rwanda will be contributing to help in upskilling local talents. By 2024, the 30,000-square-meter facility is expected to employ about 100 local staff who will run the production and all associated laboratory and quality assurance tasks on site<sup>14</sup>.

## Organizations and associations

The **Rwanda National Pharmacy Council** (NPC, <http://www.pharmacycouncil.rw>) is an independent statutory organization accountable for the regulation of pharmacy professionals.

**Rwanda Food and Drugs Authority** (RFDA, <https://www.rwandafda.gov.rw/home>) is responsible for ensuring quality and regulating of medical products, veterinary medicines, vaccines and other biological products for the population or Rwandans.

**Rwanda Development Board** (RDB, <https://rdb.rw>) is a government institution whose mandate is to accelerate Rwanda’s economic development by enabling private sector growth.

The **Rwanda Ministry of Health** (MOH, <https://www.moh.gov.rw/>) has the mission to provide and continually improve affordable promotive, preventive, curative and rehabilitative health care services of the highest quality, thereby contributing to the reduction of

<sup>11</sup> Newtimes – <https://www.newtimes.co.rw/news/innovation-fund-launched-rwanda>

<sup>12</sup> Weforum: <https://www.weforum.org/agenda/2022/07/rwanda-is-tackling-digital-development-challenges-and-succeeding/>

<sup>13</sup> Timesaerospace: <https://www.timesaerospace.aero/features/airports/qatari-boost-for-rwandas-new-airport>

<sup>14</sup> Genengnews: <https://www.genengnews.com/topics/bioprocessing/africas-first-mrna-vaccine-manufacturing-facility-breaks-ground/>

poverty and enhancing the general well-being of the population.

**Rwanda Biomedical Centre** (RBC, <https://rbc.gov.rw>) promotes high quality, affordable and sustainable health care services to the population through evidence-based interventions and practices guided by ethics and professionalism.

**Rwanda Medical Supply Limited** (RMS, <https://www.rmsltd.rw>) is a large-scale corporation created and owned by the government of Rwanda. RMS pursues the objective of ensuring availability of medicines, medical supplies and consumables in the right quantity, with the acceptable quality, to the right place and customers, at the right time and with optimum cost to the Rwandan population.

## Contacts

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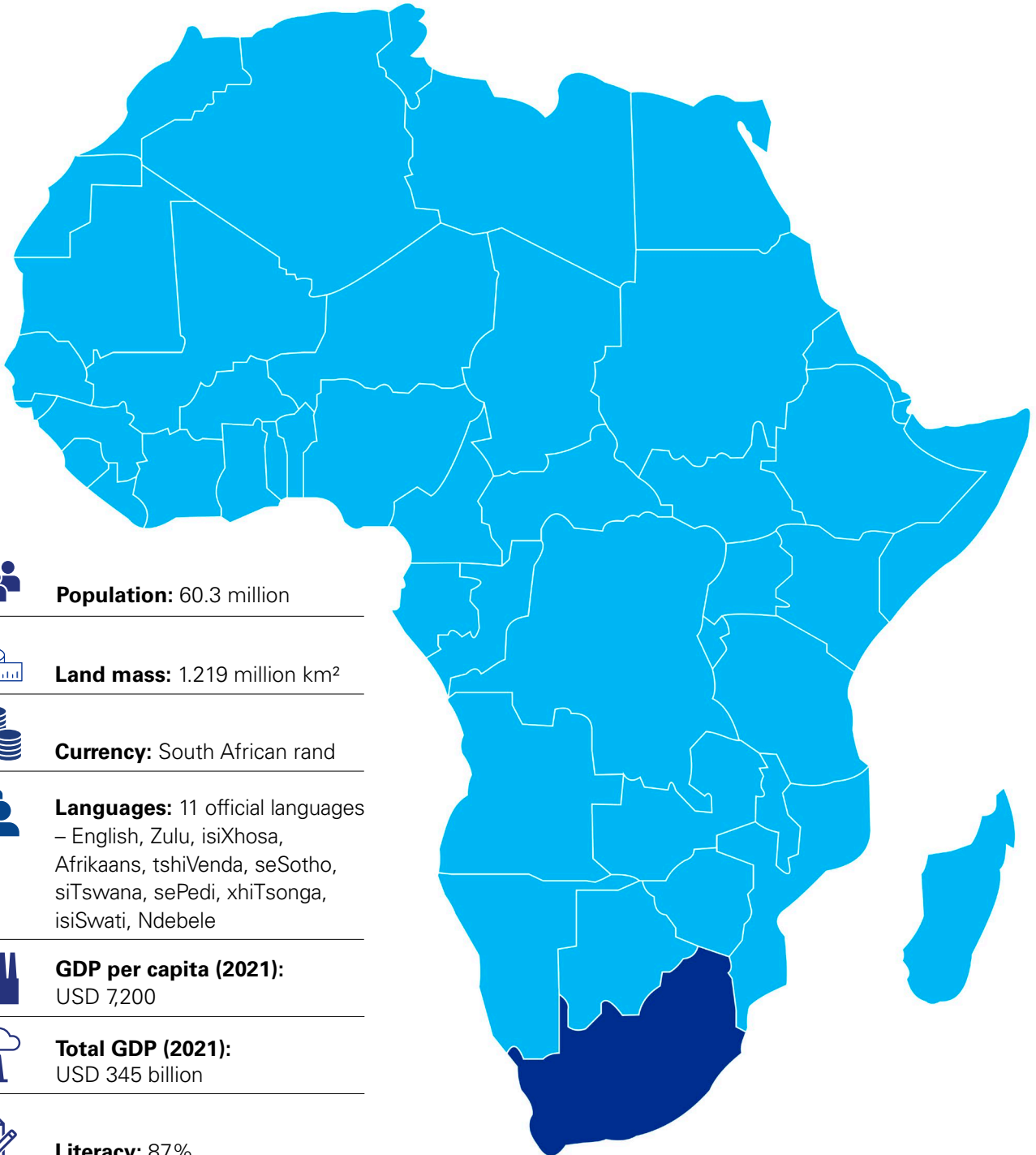
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<https://home.kpmg/xx/en/home/about/offices/kigali-1.html>



# South Africa



**Population:** 60.3 million



**Land mass:** 1.219 million km<sup>2</sup>



**Currency:** South African rand



**Languages:** 11 official languages  
– English, Zulu, isiXhosa,  
Afrikaans, tshiVenda, seSotho,  
siTswana, sePedi, xhiTsonga,  
isiSwati, Ndebele



**GDP per capita (2021):**  
USD 7,200



**Total GDP (2021):**  
USD 345 billion



**Literacy:** 87%



**Moody's credit rating:** Ba2



**System of government:**  
Presidential





**South Africa is  
leading in R&D and  
manufacturing for  
Life Science in  
Africa.**



# Snapshot of South Africa

South Africa is an ideal landing spot for life sciences businesses in Africa. The country's infrastructure is by far the most advanced on the continent, with ambitious plans for further investment and development over the coming decades. This will facilitate further growth and opportunities across South Africa's multitude of industries. Major business opportunities exist in healthcare technology, cleantech, financial technology, infrastructure and manufacturing in South Africa and beyond.<sup>1</sup>

## South African healthcare market

The South African healthcare market consists of two broad segments: private and public. The public sector is fully funded by government, while the private sector is funded by a combination of private medical schemes, government rebates, out-of-pocket contributions and short-term insurance products. There are significant differences in the overall access, quality and efficiency of care across the two segments, highlighting the country's significant healthcare challenges.

### Public sector

Government-operated and funded healthcare institutions serve approximately 85% of the South African population. Healthcare is offered for free or on a sliding scale based on income levels. Health services are split into nine provincial health departments who are responsible for the day-to-day delivery of healthcare services and procurement of medical supplies and devices.

Significant human resource constraints, along with supply and infrastructure constraints have led to poor patient outcomes and waiting times.

The public health care system is structured as a three-tier system:

- Primary health care
- Secondary health care
- Tertiary health care

### Private sector

Cost of private healthcare is prohibitively high for the majority of South Africans, with only 15% of the population registered as members of a medical scheme which is necessary for accessing private healthcare.

The cost of healthcare is primarily funded through private members who contribute to medical schemes, short-term insurance products and out-of-pocket contributions. In addition, the costs are subsidized by government through a small rebate, which results overall in significantly more funding per patient in the private sector.

The quality of private healthcare is often considerably higher than the public sector due to the relatively higher levels of funding available to this sector.

At the hospital level, the market is highly concentrated, with three main large hospital groups dominating the market. Primary health care is typically offered by small, independent healthcare practices.

## International rankings

- South Africa's economic freedom score is 56.2, making its economy the 112th freest in the **2022 Index of Economic Freedom** (<https://www.heritage.org/index/country/southafrica>).
- According **IMD 2022**, South Africa scores particularly well in R&D with a high number of female researchers and high number of scientific publications <https://www.imd.org/globalassets/wcc/docs/wco/pdfs/countries-landing-page/za.pdf>.
- The **Insead Global Talent Competitiveness Index 2022** (<https://www.insead.edu/faculty-research/research/gtci>) ranks South Africa as one of most competitive countries in Sub-Saharan Africa to attract qualified workforce.

## International Connectivity

- South Africa is part of Southern African Customs Union (SACU, <https://www.sacu.int>) and the Southern African Development Community (SADC, <https://www.sadc.int>) Free Trade Agreement.
- South Africa also has negotiated the European Union-South African Trade and Development Cooperation Agreement (<https://eur-lex.europa.eu/EN/legal-content/summary/trade-development-and-cooperation-agreement-tdca-with-south-africa.html>).
- Additionally, South Africa has concluded agreements with the European Free Trade Association (EFTA), the United Kingdom and Mercosur.
- South Africa is part of the Tripartite Free Trade Area Agreement (COMESA EAC SADC COMESA-EAC-SADC Tripartite).

<sup>1</sup> Swiss Business Hub for Southern Africa: <https://www.s-ge.com/en/company/swiss-business-hub-south-africa>



- South Africa is also a member of the newly launched African Continental Free Trade Area (AfCFTA <https://au-afcfta.org>).
- South Africa is the only African member in the **G20** group and has continued to promote its interests and that of the African continent at this gathering of leading global economies<sup>2</sup>.

## Key processes to establish a pharmaceutical manufacturing plant

Licenses to manufacture, import or export, or act as a wholesaler or distribute medicines are issued in accordance with the requirements of the Medicines and Related Substances Act. Applications should be submitted to **South African Health Products Regulatory Authority** (SAHPRA, <https://www.sahpra.org.za>). SAHPRA is the new organization which replaced the previous Medicines Control Council (MCC) which was notorious for its delays and inefficiencies. SAHPRA's guidelines of June 2022 on how to apply for a license to manufacture, import and/or export medicines and scheduled substances provides that a manufacturer's license is required for both total and partial manufacture, and for various processes of dividing up, packaging or presentation. However, such a license is not required for preparation, dividing up, packaging, or presentation where these processes are carried out solely for retail supply, by or under the supervision of a pharmacist in a registered community pharmacy or hospital pharmacy.

Note that SAHPRA is also responsible for the issuing of licenses for medical device establishments and medical devices (Medical Devices [sahpra.org.za](https://www.sahpra.org.za)). The licensing categories are: manufacturer licenses, distributor licenses and wholesaler licenses. No medical device may be manufactured, distributed, imported, exported or sold without a valid SAHPRA license.

## Tax and other incentives for manufacturing activities

The national government provides many incentives for companies planning to set up manufacturing operations in South Africa. These include loans and grants which are put in place by the department of trade industry and competition (DTIC, <http://www.thedtic.gov.za>) and the South African Revenue Service (SARS, <https://www.sars.gov.za>).

Incentives are also made available for companies at the regional level where several special economic Zones (SEZ) have been established. The SEZs typically provide for a

lower corporate tax rate of 15% if at least 90% of the income is derived from the carrying on of business within the SEZ, an accelerated 10-year tax allowance on buildings within the SEZ and VAT and customs relief if also located within a customs-controlled area.

**Of particular interest is the 150% tax allowance in respect of qualifying expenditure in respect of pre-approved research and development activities.** South Africa specifically includes the conduct of clinical trials (as defined by the Department of Health) as qualifying activities for the purposes of the R&D tax allowance.

The Technology and Human Resources for Industry Program (THRIP, <http://www.thedtic.gov.za/financial-and-non-financial-support/incentives/technology-and-human-resource-for-industry-programme>) is a cost-sharing grant incentive which aims at increasing the number of people with appropriate skills in the development and management of research-based technology for improved industry competitiveness. It leverages collaborative partnerships between the South African government and industry (working with academia) with regard to research and development in science, engineering and technology.

A detailed overview of incentives in South Africa, including R&D incentives can be found in the **KPMG Global R+D incentive guide**: <https://home.kpmg/xx/en/home/services/tax/business-tax/global-r-and-d-incentives.html>

## Key players in the life sciences industry

South Africa is the largest manufacturer and supplier of pharmaceuticals and medical devices in Sub-Saharan Africa. Most drugs exported from larger South African pharma companies, such as Aspen, stay within the African continent.<sup>3</sup>

The country has 276 companies<sup>4</sup> licensed by the National Department of Health (<https://www.health.gov.za>) and the South African Health Products Regulatory Authority (SAHPRA, <https://www.sahpra.org.za>) to manufacture, import, export and distribute pharmaceuticals. This includes international companies operating in South Africa, major local manufacturers and large retailers.

The South African pharmaceutical and medical device industry is concentrated in Gauteng, KwaZulu-Natal and

<sup>2</sup> Switzerland Global Enterprise: <https://www.s-ge.com/en/publication/country-information/south-africa-market-information>

<sup>3</sup> Pharma manufacturing: <https://www.pharmamanufacturing.com/articles/2020/global-dose-focus-on-south-africa/>

<sup>4</sup> IPASA <https://ipasa.co.za/research-and-development-and-clinical-trials-activity-a-key-component-in-pharmaceuticals/>

the Western Cape, with emerging activities in the Eastern Cape. Pharmaceutical R&D is concentrated in the Western Cape and Gauteng, the provinces which house the country's top academic institutions.

In its Industrial Policy Action Plan (IPAP), the South African government has designated the pharmaceutical industry as a priority sector and has installed several mechanisms and measures that seek to increase local production of pharmaceuticals.<sup>5</sup> According to the International Finance Collaboration (IFC), particularly the manufacturing of generic drugs and APIs should become a major focus for South Africa.<sup>6</sup>

Examples of life sciences manufacturing companies in South Africa include (selection):

**Aspen Pharmacare** (<https://www.aspenpharma.com>) – Africa's largest pharma company – is one of the key players in the South African market, having developed and manufactured the continent's first generic antiretroviral (ARV) drug. Their manufacturing site is in Gqeberha (formerly Port Elizabeth) in the Eastern Cape employing 9,100 employees. The location is considered a growing hub for life sciences.

**Adcock Ingram** (<https://www.adcock.co.za>) manufactures and markets healthcare products to both the private and public sectors. This leading South African pharmaceutical conglomerate has three local manufacturing sites for high-volume liquids, tablet and capsule manufacturing and medical grade sheeting for sterile and blood collection bags.

**Sun Pharma South Africa** (<https://sunpharma.com/south-africa/9>) is engaged in the sale and distribution of generic prescription, over the counter (OTC) and originator prescription products. The entity is ranked as top generic pharmaceutical companies in South Africa. With a state-of-the-art production facility in Roodepoort, near Johannesburg the company manufactures generic anti-retroviral (ARV) medicines.

**Cipla Medpro South Africa** (<https://www.cipla.co.za>) is the third-largest pharmaceutical manufacturer in the country. Its manufacturing plant is located in Durban and employs a staff of 500.

**Sanofi South Africa's** (<https://www.sanofi.co.za>) manufacturing site was established in 1972. It is strategically placed in Pretoria. The is a global center of

excellence in the production of products for the South African and global markets.

**Afrigen Biologics and Vaccines** (<https://www.afrigen.co.za>) is a Cape Town-based biotechnology company strategically directed, supported and capitalized by Avacare Healthcare Group and the Industrial Development Corporation (IDC) of South Africa. Afrigen drives a business strategy focusing on product development, bulk adjuvant manufacturing, and supply and distribution of key biologicals to address unmet healthcare needs.

## Clinical trials

South Africa offers attractive conditions for conducting clinical trials on the African continent. The Clinical Trial Unit of the South African Health Products Regulatory Authority (SAHPRA, [www.sahpra.org.za/clinical-trials/](http://www.sahpra.org.za/clinical-trials/)) provides legal framework for the review of clinical trials and bioequivalence studies for human participants and recommends approval of the conduct of clinical trials.

Of particular interest is the 150% tax allowance in respect of qualifying expenditure for pre-approved research and development activities, which specifically includes the conduct of clinical trials (as defined by the Department of Health) as qualifying activities for the purpose of the R&D tax allowance.

Sites for clinical trials/research in South Africa have increased over the years. The establishment of these trials occurred because of the diseases prominent in the country. This has given rise to partnership with local government with the **Clinic Research Institute of South Africa** (CRISA, <https://crisa.org.za>) being at the forefront of clinical trials in Kwa Zulu Natal. CRISA conducts research in therapeutic areas, HIV/AIDS and TB in collaboration with the Department of Health. The institute was formed with the aim of integrating clinical research towards the clinical pathway for the iLembe health district hospitals and clinics.

## Infrastructure and logistics

According to the **Africa Regional Integration Index** (<https://www.integrate-africa.org/>), South Africa is the continent's most highly ranked country on the infrastructure dimension. It has the best flight connections within Sub-Saharan Africa, giving its citizens and the citizens of the rest of the region the possibility of moving efficiently across the continent and internationally.

<sup>5</sup> <https://ispe.org/pharmaceutical-engineering/january-february-2019/south-african-pharma-industry-workforce-appraisal-proposed-development>

<sup>6</sup> IFC: [https://www.ifc.org/wps/wcm/connect/news\\_ext\\_content/ifc\\_external\\_corporate\\_site/news+and+events/news/insights/africa-local-pharma-production](https://www.ifc.org/wps/wcm/connect/news_ext_content/ifc_external_corporate_site/news+and+events/news/insights/africa-local-pharma-production)

World-class cities such as Cape Town feature excellent general infrastructure including **top-notch digital infrastructure**: South Africa is ranked second for having Africa's fastest internet speeds, with Cape Town boasting easy-to-find, reliable and fast wireless internet. For this and because of the large talent pool, Cape Town has been acknowledged as one of Africa's leading digital cities.

KwaZulu-Natal, the second largest local economy in the country, offers easy access to South Africa's two largest ports – Durban and Richards Bay – and King Shaka International Airport as well **world-class transport and telecommunications infrastructure**.

Johannesburg is an internationally renowned and vibrant metropolis, with over 5.5 million inhabitants. Johannesburg generates 16 percent of South Africa's GDP and employs 12 percent of the national workforce. Its infrastructure matches leading first world cities, yet the cost of living is far lower. With its **strong financial infrastructure**, the city is recognized as a leading financial center in Sub-Saharan Africa and is home to 74 percent of South African corporate headquarters.

Among the many SEZ in existence in South Africa there are two which have been recognized to being particularly well positioned for life sciences-related activities:

**Atlantis SEZ** (<https://atlantiszez.com>) is located just 40 kilometers outside of Cape Town in **Western Cape**. With easy access to major roads and Cape Town International Airport, it is perfectly positioned for manufacturing industries.

**Dube Trade Port** (<https://dubetradeport.co.za>) in Kwa Zulu Natal has established a pharmaceutical and medical cluster and is focusing on attracting manufacturers of biologics and active pharmaceutical Ingredients (APIs).

## Talent development

South Africa is the leading country in Africa for scientific research in life sciences, both for academic education and for R&D collaboration between industry, international organizations and universities.

The 2022 **Academic Ranking of World Universities** (ARWU, [www.shanghairanking.com](http://www.shanghairanking.com)) ranks the best 1,000 universities in the world – including nine located in South Africa. The University of Cape Town is placed inside the top 300 institutions globally. The University of the Witwatersrand is second locally, ahead of Stellenbosch, the University of Johannesburg and the University of Pretoria<sup>7</sup>.

Examples of collaboration between the private sector and South African universities include the collaboration announced in June 2022 between **Afrigen Biologics and Vaccines** (<https://www.afrigen.co.za>) to establish a vaccine technology transfer hub. The Afrigen consortium includes several academic institutions, such as the South African Medical Research Council, the University of the Witwatersrand, North-West University, the National Institute of Communicable Diseases, and the newly established Centre for Epidemiological Research and Innovation (CERI, <https://ceri.africa>)<sup>8</sup>.

In July 2022, the **Science Diplomacy Capital for Africa** (SDCfA, <https://www.africasciencediplomacy.org>) initiative was launched in the city of City of Tshwane Metropolitan Municipality. This initiative seeks to promote science collaborations across Africa by means of technological advancements and human connections<sup>9</sup>. This was initiated by the Department of Science and Innovation (DSI) and hosted by the Council for Scientific and Industrial Research (CSIR).

In June 2021, the **World Health Organization** (WHO) and its COVAX partners announced that they were working with a South African consortium comprising Biovac, Afrigen Biologics and Vaccines, a network of universities and the Africa Centre for Disease Control and Prevention (CDC) to establish a first COVID mRNA vaccine technology transfer hub<sup>10</sup>.

The **South African Medical Research Council** (SAMRC, <https://www.samrc.ac.za>) is considered the largest local funder for the research in the country. The entity was set up to deal with the health challenges of the country, with more focus on the top ten causes of mortality, co-morbidities, disability and associated risk factors. Their scope of research extends to laboratory investigations, preclinical and clinical research, and public health studies.

**CAPRISA** (<https://www.caprisa.org>) is an iconic research-based facility in South Africa. CAPRISA was formally established in 2002 under the NIH-funded Comprehensive International Program of Research on AIDS (CIPRA) by five partner institutions; University of KwaZulu-Natal, University of Cape Town, University of Western Cape, National Institute for Communicable Diseases and Columbia University in New York.

<sup>7</sup> These are the 9 best universities in South Africa – with one shooting up the global rankings ([businessstech.co.za](http://businessstech.co.za))

<sup>8</sup> Reuters: <https://www.reuters.com/business/healthcare-pharmaceuticals/south-africa-afrigen-partners-with-us-mrna-vaccine-research-2022-07-08/>

<sup>9</sup> <https://www.africasciencediplomacy.org/>

<sup>10</sup> WHO: <https://www.who.int/news/item/21-06-2021-who-supporting-south-african-consortium-to-establish-first-covid-mrna-vaccine-technology-transfer-hub>



## Organizations and associations

There are several associations representing the pharmaceuticals, biotech and medtech industry and professionals from this industry in South Africa. Examples include:

The **Innovative Pharmaceutical Association South Africa** (IPASA, <https://ipasa.co.za>) is an association of leading international companies dedicated to researching and developing novel medications, medical devices and diagnostic tools. As an association, IPASA aims to promote a sustainable environment for the pharmaceutical industry to invest in the research and development of innovative pharmaceuticals, contribute to a patient-centered health system and bring the benefits of breakthrough treatments to patients across South Africa.

The **South African Medical Technology Industry Association** (SAMED, [www.samed.org.za](http://www.samed.org.za)), founded in 1985, is a not-for-gain industry association committed to advancing patient care through MedTech. SAMED is committed to providing the MedTech industry with a **collective, objective and credible platform** for engagement with all stakeholders.

**Medical Device Manufacturers of South Africa** (MDMSA, [www.mdmsa.org.za](http://www.mdmsa.org.za)) is an association of companies that manufacture medical devices within South Africa. It is an association member of SAMED representing local manufacturers only.

The **Council for Scientific and Industrial Research** (CSIR, [www.csir.co.za](http://www.csir.co.za)) is an organization promoting industrial biotechnology in South Africa, both in terms of industrial processes and products, and as an enabling factor in the growth of the country's bioeconomy.

The **South African Association for Pharmacists in Industry** (SAAPI, [www.saapi.org.za](http://www.saapi.org.za)) is a sector of the Pharmaceutical Society of South Africa (PSSA), and a not-for-profit association serving its members by providing scientific, technical and regulatory skills development as well as guidance on policy and scientific matters through the pharmaceutical lifecycle.

The **Southern African Pharmaceutical Regulatory Affairs Association** (SAPRAA, [www.sapraa.org.za](http://www.sapraa.org.za)) is a society of professionals, largely pharmacists, involved in the area of health product/medicine regulation in Southern Africa. The majority of members work in the pharmaceutical industry or are pharmaceutical consultants.

**Africa Bio** ([www.africabio.com](http://www.africabio.com)) is an independent, non-profit biotechnology stakeholders' association for the safe, ethical, and responsible research, development, and application of biotechnology and its products. This includes generic and biosimilar medicines.

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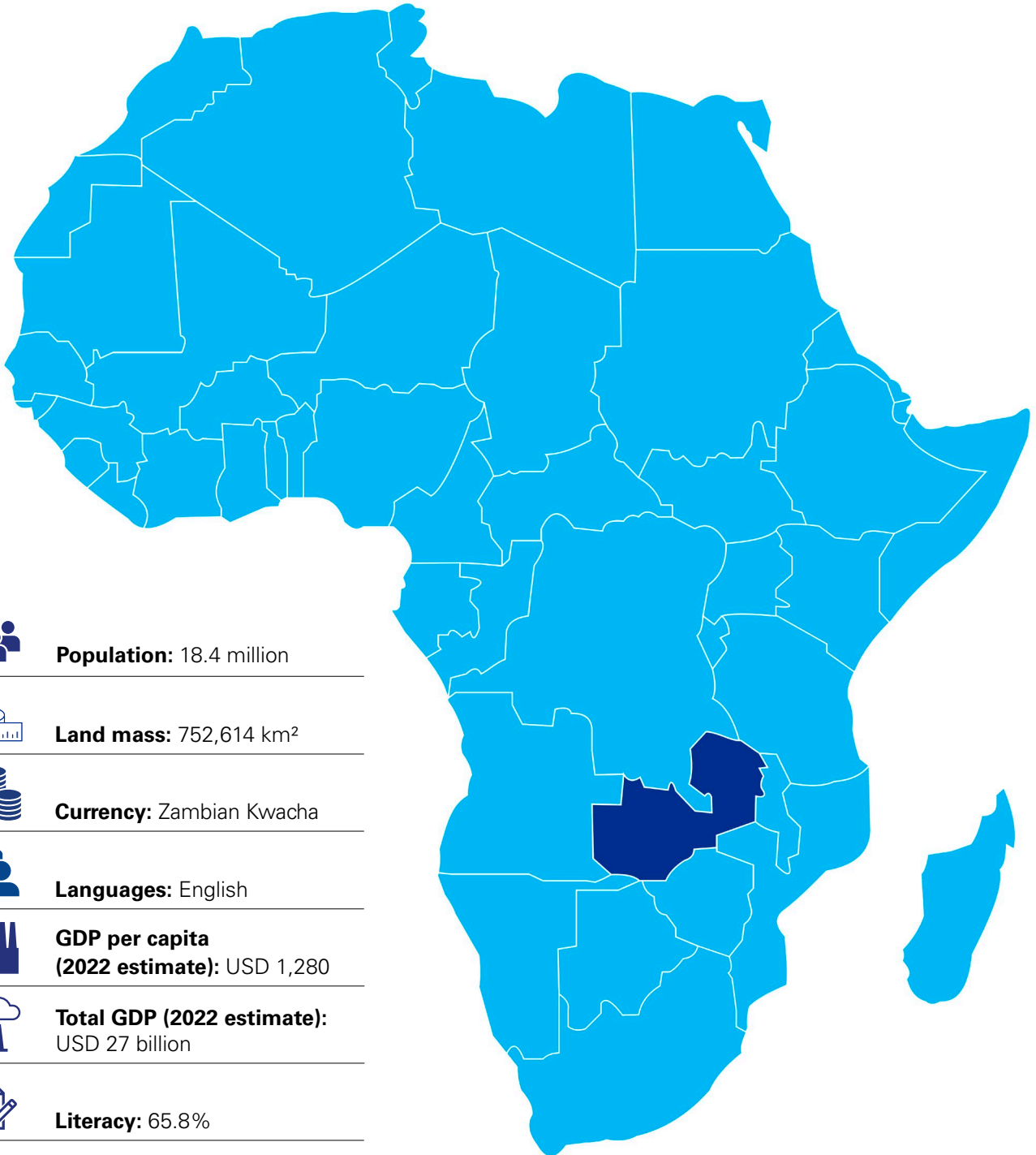
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KPMG South Africa - KPMG South Africa  
([home.kpmg](http://home.kpmg))

# Zambia



**Population:** 18.4 million



**Land mass:** 752,614 km<sup>2</sup>



**Currency:** Zambian Kwacha



**Languages:** English



**GDP per capita  
(2022 estimate):** USD 1,280



**Total GDP (2022 estimate):**  
USD 27 billion



**Literacy:** 65.8%



**Moody's credit rating:** B1



**System of government:**  
Multiparty democracy





**Several  
pharmaceutical  
manufacturers  
have recently  
started operations  
in Zambia.**



# Snapshot of Zambia

According to US Department of Commerce<sup>1</sup>, Zambia is a politically stable, multi-party democracy, rich in natural resources, with an estimated population of 18.38 million, 42 percent of which live in urban areas. Zambia, just as some other the countries on the continent, is not able to produce most medications to supply its population and depends largely on medical imports from India. Zambia has a developing private and public health care system that provides diagnostic and curative medical services. Zambia benefits from extensive US government assistance, primarily through the United States President's Emergency Plan for AIDS Relief (PEPFAR), to scale-up integrated prevention, care and treatment programs focused on achieving HIV epidemic control.

## International rankings

Zambia is ranked 85 among 190 economies in the World Bank (<https://www.worldbank.org/en/home>) "Ease of doing business ranking 2019" and comes 10th in Africa<sup>2</sup>.

According to the World Economic Forum<sup>3</sup>, the Zambian kwacha is the best performing currency in the world against the US dollar from January 2022 to September 2022. Inflation is down at 10%.

According to Freedom House (<https://freedomhouse.org>), Zambia is categorized "Partly Free" in the "Freedom in the World 2022" ranking.

## International connectivity

Zambia is a party to various trade agreements, including the **Common Market for Eastern and Southern Africa** (COMESA, <https://www.comesa.int>), the **Southern Africa Development Community** (SADC, <https://www.sadc.int>) and the **Continental Free Trade Area** (CAFTA, <https://www.comesa.int>).

The government has also signed double taxation agreements with various countries, and these agreements provide for more favorable tax rates. These include major trading partners such as Botswana, Canada, China, Denmark, Finland, France, Germany, India, Ireland,

Italy, Japan, Kenya, Netherlands, Norway, South Africa, Sweden and Switzerland.

## Key processes to establish a pharmaceutical manufacturing plant

Setting up a business in Zambia is a straightforward process that can be achieved in a short time frame. Incorporating a company with the **Patents and Companies Registration Agency** (PACRA, <https://www.pacra.org.zm>) can be done within 2-3 working days and tax registrations with the Zambia Revenue Authority can be completed within 1-2 working days (ZRA, <https://www.zra.org.zm>).

There are no sectors that are barred to foreign investors and Zambian legislation does not provide any restrictions on the percentage of equity that might be held by a foreign investor.

The government welcomes investors across sectors and the laws relating to investment provide investment incentives and protection – to attract increased investment and international trade, as well as increased domestic economic growth.

## Regulatory framework for life science companies in Zambia

The Zambia Medicines Regulatory Agency (ZAMRA, <https://www.zamra.co.zm>) is responsible for licensing and regulation of medicines for use in Zambia. It is also tasked with monitoring their use and adherence to standards of quality, throughout manufacturing, importation, and exportation.

The list of products approved for use in Zambia may be found on the national medicines register produced by ZAMRA every year. ZAMRA is also responsible for inspecting manufacturers and importers to ensure their compliance with local regulations.

<sup>1</sup> International Trade Administration: <https://www.trade.gov/country-commercial-guides/zambia-market-overview>

<sup>2</sup> Worldbank: <https://data.worldbank.org/indicator/IC.BUS.EASE.XQ?locations=ZM>

<sup>3</sup> World economic forum: <https://www.weforum.org/agenda/2022/09/zambian-kwacha-secret-inflation-strengthening-africa-money>

## Tax and other incentives for manufacturing activities

Manufacturing is not considered one of the priority sectors in the country and no tax incentives are currently enjoyed under the manufacturing sector. However, non-fiscal incentives can be enjoyed. These include:

- Investment guarantees and protection against state nationalization
- Free facilitation for application of immigration permits, secondary licenses, land acquisition and utilities

### Brief overview of the tax system in Zambia

Zambia principally operates a source-based system of taxation. Therefore, strictly speaking, any income which is deemed to be from a source within Zambia will be liable to tax in Zambia.

Upon registration for taxes, a single taxpayer identification number (TPIN) is provided to a taxpayer. The TPIN is linked to all the taxpayer's tax types with the Zambia Revenue Authority.

The following taxes are payable in Zambia:

- Corporate income tax
- VAT/VAT reverse charge
- Withholding tax
- Pay-as-you-earn (PAYE)
- Property transfer tax
- Customs and excise duties

### Corporate income tax

Companies registered in Zambia with an annual turnover of ZMW 800,000 or above should register for corporate income tax; and companies with an annual revenue below ZMW 800,000 are required to register for turnover tax. Companies will be automatically switched from turnover tax to corporate tax when the ZMW 800,000 threshold is exceeded.

The standard corporate income tax rate in Zambia is 30%. A company's taxable income is based on the financial statements prepared for the period of account as adjusted for tax purposes (i.e. disallowance of depreciation and expenditure specifically disallowed for tax purposes and calculation of capital allowances and deductions allowed for tax purposes etc). The rate of withholding tax deductible on payments may be reduced where there is a tax treaty in place between Zambia and the recipient country.

## Investment licenses

There are no limits on the amount of investment required to be made for an investment license, however, there are some minimum investment thresholds to qualify for certain benefits in priority sectors, specifically:

- No less than USD 250,000 in order to qualify for non-fiscal incentive
- No less than USD 500,000 in order to qualify for special tax incentives for Priority Sectors or products located in a Multi facility economic zones

The investment license is valid for ten years from the date of issue. The investor may apply for renewal of the investment license before the date of its expiry. Priority sectors for investment incentives include construction of health centers as defined under the Health Professions Act of 2009.

## Key players in the life sciences industry

**NRB group** (NRB Pharma Zambia Ltd.) opened a manufacturing facility in 2017. The plant is designed to produce anti-bacterial, anti-biotics, anti-tuberculosis tablets etc..

At the beginning of 2022 it was announced that **International Drug Company LTD** (<https://idclzambia.com/kabwe>) would be expanding its footprint in Zambia. The organization has a plant in Lusaka. The expansion of their facilities will include a microbiology laboratory and a physical-chemical laboratory and warehouse facilities on the premises.

### Mylan Laboratories Zambia Limited

(<https://www.lsmfz.co.zm/gallery/mylan-laboratories>) is based with its manufacturing plant at Lusaka MFEZ. Other manufacturers and distributors of pharmaceutical products include:

- **Yash Life Science** (<http://www.yashlifesciences.com>)
- **Missionpharma Zambia Distribution** (<http://missionpharma.com/>)

## Infrastructure and logistics

Zambia has four international airports: Kenneth Kaunda International Airport, Simon Mwansa Kapwepwe International Airport, Harry Mwaanga Nkumbula International Airport and Mfuwe International Airport. Three of Africa's main airlines, Kenya Airways, South African Airways and Ethiopian Airlines, provide the majority of traffic on regional routes from Kenneth Kaunda

<sup>4</sup> Zambia Invest: <https://www.zambiainvest.com/transport>

(Lusaka) International Airport<sup>4</sup>. The Zambian government has set a focus on improving infrastructure at all airports. Some of the developments in progress include the establishment of terminals, runways and auxiliary facilities around the airports such as shopping malls, hotels, etc.

### Road connectivity

Of the road structure spanning approximately 37,000 km, over 10,000 km is surfaced to class 1 standard and is bituminous. Some toll routes that form the backbone of Zambian national road network include Kipri Mposhi to Nakonde, Solwezi to Kazungula and Lusaka to Mchinji via Chipata.

### Railway connectivity

In Zambia, railways are the leading transportation mode for goods on the international and local routes. The total length of the Zambian railway network is more than 2,922 kilometers. Of these, 900 kilometers are main lines while the rest of the network is branch line railway. To develop the surface transport sector, the Zambian government is currently focused on developing the railway network (<https://www.zambiainvest.com/transport>).

### Free trade zones

To date the Zambian government has declared six areas as multi-facility economic zones (MFEZs) and/or industrial parks. Examples are described below:

**Lusaka South-MFEZ** (Home – LSMFEZ Website) provides serviced land to investors such as roads, water, sewerage line, power lines and telecommunication infrastructure. NRB pharma and Mylan Laboratories are currently located in the zone.

**Lusaka East MFEZ** (Home - LSMFEZ Website) is situated 2 km adjacent to the Lusaka International Airport and covers an area of 570 hectares. The zone aims to attract investment in processing, manufacturing, light industries, logistics and real estate.

**Roma Park** (Home | Roma Park | Zambia Commercial Property For Sale ([romaparkproperties.com](http://romaparkproperties.com)) is the first private commercial property zoned as an industrial park in Zambia. The park boasts 120 hectares of land consisting of residential and commercial lots.

## Organizations and associations

**Zambia Association of Manufacturers** (ZAM, <http://zam.co.zm>) is a business association which represents the interests of the entire manufacturing sector and other related economic and/or production sectors in Zambia.

The **National Health Research Authority** (NHRA, <https://www.nhra.org.zm>) provides regulatory services for health research in Zambia.

**Zambia Regulatory Authorities** (ZAMRA, <https://www.zamra.co.zm>) is tasked with ensuring that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

**Strategic Centre for Health Systems Metrics & Evaluations** (SCHEME, Strategic Centre for Health Metrics & Evaluation (SCHEME) at the University of Zambia School of Public Health – HBNU Fogarty Global Health Training Program ([harvard.edu](http://harvard.edu))) is an organization comprising public health staff from the University of Zambia and associate partners such as Harvest University, BU CGHD and the Centre for Family Health Research in Zambia (CFHRZ)

The **Pharmaceutical Society of Zambia** (PSZ, PSZ – Pharmaceutical Society Of Zambia) is a representative organization that was formed to enable pharmacists to deploy their professional expertise in the care of patients.

The **Ministry of Health** (<https://www.moh.gov.zm>) aims to provide effective quality healthcare services as close as possible to patients' family. This ensures equity of access to health service delivery and contributes to the human and socioeconomic development. The ministry also targets the attainment of Sustainable Development Goals on health and other national health priorities.

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<https://home.kpmg/xx/en/home/about/offices/lusaka-1.html>



# About us

KPMG is a global network of independent member firms providing Audit, Tax and Advisory services. We operate in 147 countries and territories, collectively employing more than 219,000 people, to serve the needs of business, governments, public-sector agencies, non-profits and – through member firms’ audit and assurance practices – the capital markets. We lead with a commitment to quality and consistency across our global network. In a world where rapid change and unprecedented disruption are the new normal, we inspire confidence and empower change in all we do.

KPMG has a dedicated practice for the Healthcare & Life Sciences industry, and the variety of public-private partnerships therein. We support payers/providers with reform programs, ranging from care system redesign to connected health, operational excellence, and workforce capacity development. We support pharma, biotech and medtech companies in achieving organic and inorganic growth ambitions, streamlining operational structures, and ensuring regulatory compliance. We believe in the mission of improving population health and, utilizing a global network model, follow the “something to teach, something to learn” philosophy of sharing best practices from around the world.



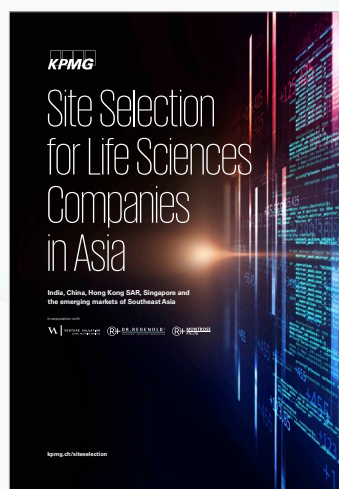
# Other KPMG publications

A series of publications from KPMG provides insights, analysis and studies from the featured countries in this report. All publications are available online. For more information, please click on the links below.



## Site Selection for Life Sciences Companies in Europe

Choosing the right location when setting up or expanding operations is no easy task. Read our insights into the most important things to consider.



## Site Selection for Life Sciences Companies in Asia

Navigate the landscape of Asia's most dynamic and diverse Life Sciences markets.



## R&D 2030

Reinvent innovation and become an R&D front-runner by 2030. Thriving on disruption series

## KPMG Blog

Thought Leadership and insights on regional and global business issues from KPMG Switzerland's subject matter experts.

📧 [kpmg.ch/blog](https://kpmg.ch/blog)

## KPMG Expert Talk

Podcasts addressing some of the most pressing issues and opportunities of today's business world.

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## Industry Data

Venture Valuation  
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