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The Medical and Laboratory Equipment and Technologies Market in East Africa - Report

africon GmbH

Imprint

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List of acronyms

AfDB	African Development Bank
AIDS	Acquired Immuno-Deficiency Syndrome
API	Active Pharmaceutical Ingredients
BUFMAR	Office for the Non-for-profit Medical Facilities in Rwanda
CDC	Centre for Disease Control
CHBI	Community-based health insurance
CHWs	Community Health Workers
COVID-19	Coronavirus disease 2019
EAC	East African Community
EU	European Union
FBO	Faith-based organization
FDI	Foreign Direct Investment
GAHF	Government Assisted Health Facility
GDP	Gross Domestic Product
GOK	Government of Kenya
GOU	Government of Uganda
HCI	Human Capital Index
HIS	Health Information System
HIV	Human Immuno-Deficiency Virus
ICT	Information and communication technology
ISO	International Organization for Standardization
JMS	Joint Medical Stores
KEBS	Kenya Bureau of Standards
KEMSA	Kenya Medical Supplies Authority
MCH	Maternal child health
MDA	Ministries, Departments and Agencies
MEDS	Mission for Essential Drugs and Supplies
MoH	Ministry of Health
MSH	Management Sciences for Health
NCD	Non communicable disease
NDA	National Drug Authority, Uganda
NDP	National Drug Policy
NGO	Non-governmental organization
NHP	National Health Policy
NMHCP	National Minimum Health Care Package
NMS	National Medical Store
NPCs	Non-physician clinicians
ODA	Official Development Assistance
PBF	Performance-based financing
PHC	Primary healthcare
PNFP	Public and private not-for-profit institutions
PPB	Pharmacy and Poisons Board, Kenya
PPP	Public-private partnership
PRIMS	Pharmaceutical Registration Information Management System
RBC	Rwanda Biomedical Center
RMS	Rwanda Medical Supply
RRK	Regional Referral Hospital

RSB	Rwanda Standards Board
RSSB	Rwanda Social Security Board
STD	Sexually transmitted disease
SURE	Securing Ugandans' Right to Essential Medicines
TB	Tuberculosis
TBS	Tanzania Bureau of Standards
UHC	Universal healthcare
UHF	Ugandan Healthcare Federation
UHSC	Uganda Health Supply Chain
UK DFID	UK Department for International Development
UNBS	Uganda National Bureau of Standards
USAID	United States Agency for International Development
USD	United States Dollars
UTIs	Urinary Tract Infections
WHO	World Health Organization

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Executive Summary

This study was commissioned by the East Africa Health Platform (EAHP) to evaluate the medical and lab equipment and technologies landscape in East Africa. The objective of the study was to identify trends, challenges, and opportunities for German medical and laboratory equipment and technologies suppliers in East Africa. It is also meant to enable the EAHP identify potential areas of intervention, specifically through market facilitation with the aim of promoting partnerships between relevant stakeholders in East Africa and Germany, as well as other international actors.

The study sought to gather information through interviews with key stakeholders and experts in Kenya, Uganda, Rwanda, and Tanzania (including Zanzibar). Interview partners came from a broad range of backgrounds including healthcare providers, regulators, government agencies, and medical and laboratory equipment distributors. Other sources of information used included secondary data, such as trade data, industry reports and general online research.

The study revealed a wide range of opportunities and challenges for new players looking to enter the East African medical and laboratory equipment and technologies market:

The public sector plays the biggest role in provision of healthcare services across East Africa. Public health facilities are preferred for their affordability and are usually spread out across the country. Private hospitals on the other hand are costly and usually concentrated in a few large cities. However, they do play a critical role in absorbing demand from the portion of the population willing to pay a premium for shorter wait times and in some cases higher quality of care. This reduces the burden on the otherwise heavily over-subscribed public facilities. There are also Private not-for-profit (PNFP) health providers who play a significant role in provision of health services especially to rural and poor populations. PNFP are primarily operated by faith-based organizations and in rare cases by non-religious non-governmental organizations (NGOs). In East Africa, the involvement of faith-based organizations in health care goes back over a hundred years during colonial times. Many of the first hospitals established in East Africa were church based and worked in collaboration with colonial administrations to provide health services to the population. Most of these faith-based hospitals describe themselves as existing to serve the poor, marginalized and unreached and as such their activities tend to be more concentrated and more significant in rural areas. However, despite their presence in rural setting, urban faith-based hospitals are more established than rural ones in terms of readiness for modern equipment and technologies.

Healthcare expenditure in East Africa has been on the rise over the past decade. However, it has not kept up with population and gross domestic product (GDP) growth, which has resulted in a decline in healthcare expenditure per capita and healthcare expenditure as a ratio of GDP respectively. Kenya on average spends the highest amount on healthcare per capita at USD 88, followed by Rwanda (USD 58), Uganda (USD 43) and Tanzania (USD 37). Public spending is not sufficient to meet the healthcare needs of these countries and therefore donor financing and private spending fill the funding gap. Donor dependency is very high across the region with Uganda having the highest proportion, 42% of its healthcare expenditure funded by donors, followed by Tanzania (32%), Rwanda (31%) and Kenya (16%). Private spending is mainly in the form of out-of-pocket payment and private health insurance schemes. Private insurance is limited to the formally employed while out-of-pocket payment is very common due to majority of the population being uninsured.

The health burden in East Africa is shifting from infectious to non-communicable diseases (NCDs), resulting in a double burden of disease. The rise in non-communicable diseases is associated with demographic and social changes such as globalisation, urbanization, aging population, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption. All this is happening while the countries are still struggling to tackle HIV/AIDS, malaria and tuberculosis, which have traditionally been and continue to be among the leading causes

of death in the region. This epidemiological transition from infectious to non-communicable diseases is expected to lead to an increasing demand for new medical technologies for diagnosing and managing emerging diseases such as cardiovascular diseases and diabetes.

The procurement process of medical and laboratory equipment works differently in the public and private sector. In the public sector, procurement takes a centralized approach where a single government supply chain agent is responsible for procuring, warehousing, and distributing medical commodities to all public health facilities in the respective country. In the private sector, procurement is done either directly from independent distributors or through group purchasing organizations. Group purchasing organizations bring together like-minded health sector players with the objective of leveraging the combined purchasing power of members to negotiate for favourable pricing from suppliers. This model is fast growing and is expected to be the primary channel used by majority of health facilities in the coming years.

Almost every medical and laboratory equipment used in East Africa is imported, with very limited domestic manufacturing taking place. China is the leading source of imports for medical equipment across Kenya, Uganda, Tanzania and Rwanda. However, imports from Western countries including Europe, North America and Australia, collectively still account for the largest market share. On the other hand, Germany is the leading source of imports when it comes to laboratory equipment.

Price is the most important factor considered when purchasing medical and laboratory equipment in East Africa. It is therefore not surprising that China features prominently among the leading source of imports. However, due to other factors such as brand familiarity and general perception of quality, western brands - especially those from Germany - are also preferred. Price is less of a factor in the public sector compared to the private sector. Due to the lack of profit motive, the public sector is often more interested in purchasing quality equipment, while private sector players primarily consider their bottom line. However, medical and laboratory equipment investment decisions are made much faster in the private sector compared to the public sector. Investment in the public sector is plagued with bureaucracy and conflicting priorities by the government. There are multiple stakeholders involved in the decision-making process, which often results in lengthy consultations. On the other hand, in the private sector, owners and management can make decisions with limited consultation, focusing strictly on expected return on investment and competitive edge of the health facility.

The most common way in which healthcare providers learn about new medical technology is through direct contact with vendors. All major medical and laboratory equipment suppliers have local representatives in the target markets who are responsible for increasing product awareness, answering customers' queries, providing technical advice, and introducing new products to potential clients. Other common ways in which health providers learn about new technologies are through online resources and recommendations from colleagues in their professional circles. Conferences and tradeshows are the least popular options to learn about new medical technology due to the cost and time investment needed as well as the lack of high profile medical-related tradeshows locally.

E-health is yet to be widely adopted across East Africa due to several limiting factors including cost, low digital literacy, unreliable power supply and poor internet coverage especially in rural areas. However, the respective governments in East Africa have recognized e-health as an important enabler for healthcare system strengthening and have drafted digital healthcare strategies and policies to guide the use of Information and Communication Technology (ICT) in supporting healthcare sector transformation. Some of the main policy objectives include strengthening integration of and interoperability between healthcare information systems, improving collection, management and use of data at all levels of care, improving ICT infrastructure and software support

in the health sector, as well as providing a legal framework for information and data security. E-health adoption is therefore expected to accelerate in the next few years with clear policies now in place and the continued commitment by the governments in East Africa to invest in the supporting ICT infrastructure.

Opportunities for medical and laboratory equipment

Based on trade statistics as well as interviews conducted with hospitals, medical labs and medical equipment distributors, a few segments present the best opportunities for new players looking to enter the East African market.

Imaging equipment: Based on trade data, X-ray and ultrasound equipment consistently ranks in the top 10 medical equipment imports in East Africa. In 2019, imports of X-ray and ultrasound equipment to East Africa stood at USD 49.8 million and USD 10.7 million respectively before declining 30% and 56% respectively in 2020 as health sector players held off investment due to the impact of Covid-19 on the economy. However, the economy is expected to rebound in 2021 and imports expected to recover. Imaging is expected to be a key growth segment in the coming years with 60% of hospitals interviewed confirming plans to invest in imaging equipment in the short to medium term. This segment is also one of the most attractive for European manufacturers due to strong preference for quality and reliable machines, when it comes to capital intensive and high-tech equipment. According to interviews with hospital operators, China is not yet a formidable competitor in the high-tech high-value segment but more dominant on low-value low-tech products.

Consumables: Catheters, syringes and needles are the highest imported consumables in East Africa with 2020 imports standing at USD 17.7 million USD 9.2 million USD 4.3 million respectively. Unlike capital intensive medical equipment, consumables are purchased on a regular basis and demand is relatively stable as evidenced by the marginal decline in imports in 2020 compared to 2019 indicating no significant impact from the pandemic. However, due to the low-tech nature of these products, China dominated the segment accounting for 32% of all imported catheters, syringes, and needles in 2020. Other consumables are unattractive due to presence of local manufacturers e.g., surgical masks, personal protective equipment (PPE), bandages, and dressings.

Orthopaedics: This is a large and fast-growing market segment largely driven by the high number of road traffic accidents in the region. Each year in East Africa, 2.9 people die from road traffic accidents per every 10,000 people, making East Africa among the top 15 most dangerous places to be on the road.[1] For survivors of road traffic accidents, musculoskeletal injuries are a common. This has led to a growth in demand for orthopaedic devices that are used to replace missing joints and bone as well give support to the damaged bone. There has also been an increase in the number of skilled orthopaedic surgeons which has resulted in adoption of new technologies to treat musculoskeletal conditions such as osteoarthritis and osteoporosis through procedures like hip and knee replacements. Import of orthopaedic appliances stood at USD 3.8 million in 2020 and has been growing at a steady compounded annual growth rate (CAGR) of 13.5% since 2011 and is expected to grow even faster with the increased motorization rate in East Africa which expected to result in more road traffic related injuries.

ICU equipment: The COVID-19 pandemic exposed the vulnerabilities of the East African healthcare system, and this has led to increased resources towards equipping health facilities to prepare for when a future pandemic might hit. Therapeutic respiratory apparatuses such as ventilator and oxygen therapy machines were the fastest growing segment during the pandemic, recording a 297% growth from USD 7.4 million in 2019 to USD 29.4 million in 2020. Demand is expected slowdown in 2021 with the decline of Covid-19 but continue growing at the pre-pandemic levels of 4.2% CAGR between 2012 and 2019.

[1] Trademark East Africa

Hospital furniture: The past few years have seen a boom in the construction of new hospitals especially in Kenya where multiple private hospitals have rolled out multi-billion-shilling expansion projects in order to meet the current and expected growth in demand for quality healthcare services as the country's middle-class population further grows.[2] This kind of growth is expected to result in an increasing demand for hospital furniture such as hospital beds, hospital cart and stands, bedside tables, hospital cabinet, and baby furniture. East Africa is also going to experience a double disease burden due to the increase in non-communicable diseases cardiovascular diseases, cancers and diabetes which is going to put a strain on the current health care infrastructure, thereby leading to an increased demand for hospital furniture. Hospital furniture imports stood at USD 14.3 million in 2020 and has been growing consistently at a 6% CAGR since 2012 and this is expected to continue through to 2030.

E-health: Adoption of E-health is still low in East Africa. Among the 26 interviewed health facilities mainly made up of secondary and tertiary hospitals, only 56% had an E-health system. This rate is estimated to be even lower for facilities at the primary level and below. The low adoption rate is mainly due to government bureaucracy when it comes to public health facilities as well as insufficient supporting ICT infrastructure like reliable internet and power supply. However, all the East African countries have recognized e-health as an important enabler for healthcare system strengthening and have drafted digital healthcare strategies and policies to guide the use of ICT in healthcare. This is expected to accelerate the adoption of e-health in the next few years.

E-learning: Among the 10 health training institutions interviewed in this project, only on 45% had adopted e-learning as a tool for teaching albeit in a limited capacity. The Covid-19 pandemic accelerated the adoption of e-learning, however majority of the institutions returned to in-person teaching after social distancing restrictions were lifted. These institutions pointed to challenges such as lack of reliable internet, unstable power supply and lack of e-learning-friendly content as some of the main reasons that makes e-learning adoption difficult. However, there is still a great opportunity for e-learning system providers as governments in East Africa look for solutions to address the shortage of trained healthcare workers. Governments are already recognizing the benefits of e-learning as a tool for increasing access to education. For instance, in 2007, the Kenyan government compelled higher education institutions to adopt e-learning under the country's Vision 2030 strategic plan. The intention was to increase the number of people that can access higher education, given that demand for space at higher education institutions far exceeds supply. Additionally, 70% of the health training institutions interviewed during this project that had an e-learning system expressed willingness to expand their e-learning offerings and would consider acquiring more advanced systems that would provide more engagement with students as opposed to being used only as a means of conducting lectures.

[2] Oxford Business Group

Recommendations for medical and laboratory equipment suppliers

Establish a local presence: In order to compete with the large multinationals that already dominate the medical and laboratory equipment market, proximity to customers is critical. Being locally present has several advantages including being able to control the product messaging, getting better information on customers and use-cases, as well as having more control of service quality and customer training. From 26 hospital and laboratory professional interviewed in this project, 36% of them confirmed learning about new technologies from suppliers directly and therefore a local presence would be the best way to increase product awareness and introduce new products to the market.

Identify and appoint a local distribution partner: A local distribution partner can complement the efforts of the manufacturer in the market. Using a local distributor provides several advantages including being able to leverage on the distributor's sales channels, business relationships and logistical capabilities. A local distributor also has a better understanding of the regulatory environment and can help navigate all product regulation hurdles. The ideal partner should usually be handling complementary products, selling to the buyers of greatest importance to you, cover the geographic areas that you need to reach and have the right personnel to meet the sales needs.

Target private hospitals first: Procurement in the public sector is slower compared to private sector due to the number of stakeholders involved. However, in the private sector, decisions are made much quicker due to fewer steps involved and a lot more objectivity when evaluating investment in medical and laboratory equipment. In the private sector, single sourcing is also permitted which gives new players in the market the opportunity to present a case for their product.

Take advantage of group purchasing organizations: In the private sector, group purchasing organizations are common across East Africa. These are large bulk procurers of medicines and health products that leverage on the combined purchasing power of their members to negotiate favourable contract pricing from suppliers. For new suppliers in the market, such organizations provide access to a large network of members and thereby reduce marketing cost needed to create product awareness in the market. Public procurement agencies are an alternative route for suppliers interested in the public health sector.

Future trend to watch

Private sector participation in health care is expected to increase over the next few years driven by the growing middle-class that is willing to pay a premium for better quality health services. The private sector has been on an expansion drive especially in Kenya and has even attracted to interest of international private equity investors.[3] The governments across East Africa are also pushing for more public-private partnerships (PPP). For instance, in Tanzania, municipalities can enter into service agreements with private health care providers to provide services not available at public health facilities. In some instances, the government can support the public health facility by providing and paying for health workers especially those in high priority areas like maternal and child health.[4] In Kenya, Kenyatta hospital announced plans to construct a USD 140 million seven-storey private hospital to fund public services in the parent institution under a 30-year PPP arrangement.[5] Governments in East Africa are focusing more on pro-poor health interventions especially at primary healthcare level and therefore are looking for the private sector to step in and provide specialized health services. We expect to see fewer new public hospitals being built as more funding is directed towards equipping existing health facilities as well as revamping the existing public insurance system in order to achieve universal health care.

Health expenditure is expected to increase in the next few years as East African countries commit to rolling out universal health care (UHC). According to experts, it is estimated that for East Africa to really achieve UHC, the level of public health spending would need to at least double from its current levels. East African governments of recent have increased their allocation to their respective national insurance scheme to cover the poor and vulnerable but this has not been sufficient. The roll out of UHC is also expected to face challenges as the East African economies are still reeling from the impact of Covid-19 which resulted in closing of businesses which in turn resulted in low tax revenues. UHC is expected to be rolled out in phases based on government's financial capabilities in the next few years. With more people with access to healthcare, health spending per capita is expected to increase substantially in the next few years.

Donor dependency is expected to decline especially in Kenya, Tanzania and Rwanda but remain high in Uganda. Kenya and Tanzania are classified as low-middle-income countries which make them ineligible for certain donor financing facilities as they are now perceived to be increasingly capable of financing their own development. Rwanda of recent has seen a decline in donor funding for the health sector due to improving indicators in areas of high donor interest like HIV/AIDS, tuberculosis, malaria and infant mortality. Donors have therefore redirected donor funding for Rwanda towards other more vulnerable sectors since it is still classified as a least developed country. Uganda is the heaviest reliant on donors and this is expected to remain the same in the coming years due to a high disease burden compared to its peers.

It is projected that by 2030, non-communicable diseases (NCDs) will surpass communicable diseases as the leading causes of deaths in East Africa. In 2016, 40% of all deaths were attributable to NCDs. This is expected to surpass 50% by 2030.[6] The declining of deaths from communicable diseases has been as a result of concerted efforts in making treatment and management of HIV/AIDS, Malaria and Tuberculosis more accessible and affordable. On the other hand, the rise in non-communicable diseases is associated with demographic and social changes such as globalization, urbanization, aging

[3] Standard media
[4] BMC Health Services Research
[5] FDI intelligence
[6] BMJ global health

population, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption.

Group purchasing organizations are expected to be the primary channel used by private and faith-based hospitals to source medical supplies. Group purchasing organizations aggregate procurement of medical products by hospitals under one entity in order to leverage on economies of scale to secure preferential pricing. This is especially the case for low tech and low value medical supplies such as syringes and needles which are procured in large quantities by hospitals. Capital intensive and slow-moving products are not purchased in bulk and therefore their procurement process is expected to remain the same with health facilities procuring directly from suppliers or a distributor on a need basis. Only Tanzania lacks a well-established group purchasing organization with the last one to exist ceasing operations in 2019.

The market share of Western countries in the medical and laboratory equipment segment is expected to decline as China continues making inroads in East Africa. Currently majority of imports from China are low-tech and low-value products but this is changing fast as China catches up in technology with Western countries. For instance, Mindray, one of the leading Chinese medical equipment suppliers has been able to break into the high-tech and high-value equipment segment which has traditionally been dominated by western brands such a Siemens and Philips. Western brands however are still expected to retain market share among the large and high-end hospitals and laboratories who tend to be reluctant in experimenting with unproven brands.

Direct contact with customers is expected to remain the most effective way to market medical and laboratory equipment in East Africa. Due to lack of quality trade shows in the region and the high cost of travelling internationally, medical equipment suppliers are expected to continue opening offices locally. Virtual trade shows were common during the Covid-19 pandemic period, but this is not expected to continue into 2022.

Between 2011 to 2020, the import of medical equipment saw a compounded annual growth rate (CAGR) of 4.37% while laboratory equipment saw a CAGR of 1.36%. However, year on year growth has been slowing down which can be attributed to the growth of local manufacturing especially when it comes to low-value and low-tech medical products. In the next few years, import of high tech medical and laboratory equipment is expected to see a steady increase as more investment is made in the health sector while import of low-tech equipment is expected to decline as local manufacturing output increases.

Harmonization of regulatory requirements for medical and laboratory equipment is expected to take place in the coming decade as part of the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative. The EAC MRH initiative is meant to strengthen regulatory capacity, encourage harmonization of regulatory requirements and expediting access to good quality, safe, and effective medical products. By creating a joint assessment process of medical and laboratory equipment, manufacturers would be able to receive marketing authorization in multiple EAC member states through a single application. The initiative is still in its pilot phase but is expected to be ratified within the next few years.

1. Introduction

Sub-Saharan Africa is experiencing an epidemiological transition in its disease burden from infectious to non-communicable diseases (NCDs) resulting in a double burden of disease. According to the International Finance Corporation (IFC), Sub-Saharan Africa has about 11% of the world's people, but carries 24% of the global disease burden in both human and financial costs.[7] Almost half the world's deaths of children under-five take place in Africa.[8] While infectious diseases still account for about 70% of deaths on the continent, age-specific mortality rates from chronic diseases are actually higher in Sub-Saharan Africa than in any other regions of the world, for both men and women.[9] Over the next ten years the continent is projected to experience a high increase in death rates from cardiovascular diseases, cancer, respiratory diseases, and diabetes.

East Africa is one of the main disease-ridden regions in the world. Despite strong efforts to fight communicable diseases through both internal means and external support from donors, communicable diseases still make up the largest share of deaths, as well as hospital admissions. For the EAC to achieve its Vision 2050 goals of being an upper-middle income region[10], investment in human capital development is critical and this is only possible with a strong healthcare system in place. Investing in healthcare is crucial for economic development since ill health impairs productivity, hinders job prospects, and adversely affects human capital development. Good health is therefore not only an outcome of, but also a foundation for development.

One of the areas critical to having a strong healthcare system is the availability of adequate, modern medical and laboratory equipment and technologies. The majority of healthcare facilities in East Africa, especially public facilities are severely lacking when it comes to infrastructure and equipment needed to handle the existing and emerging health challenges affecting the region. For this reason, the East Africa Health Platform (EAHP) commissioned this study to evaluate the medical and laboratory equipment and technologies landscape in Kenya, Uganda, Rwanda, and Tanzania (including Zanzibar). The study is meant to enable EAHP identify potential areas of intervention, specifically through market facilitation with the aim of promoting partnerships between relevant stakeholders in East Africa, Germany as well as other international actors in the health sector.

Methodology

The study was conducted through primary and secondary research running simultaneously. The secondary research mainly focused on local sources such as official government statistical publications, ministry of health reports, treasury budget reports, and reports from other local institutions, as well as global sources such as industry reports, World Bank, World Health Organization (WHO), United Nations Children's Fund (UNICEF), United States Agency for International Development (USAID) and other international health stakeholders.

The primary research was conducted through semi-guided, mostly open-ended questionnaires based on the terms of reference of the project. Several questionnaires were prepared based on the target respondents who included key staff at hospitals, medical labs, medical equipment distributors, government medical supplies distributors, ministries of health, medical equipment regulators and health training institutions. Prior to implementation, the questionnaires were shared, reviewed, and approved by EAHP.

[7] IFC, The business of health in Africa
[8] UNICEF, Under-five mortality 2021
[9] IHME 2021
[10] EAC vision 2050

The sample of key informants was chosen purposefully to include both public and private sector players to give a more accurate picture of the medical and laboratory equipment and technology landscapes in each of the surveyed countries. An initial list of participants was developed, shared, reviewed, and approved by EAHP. Additional participants were identified according to a snowballing methodology during the interviews. The sample size in each of the countries was between 15-20 participants. The total sample size was 80 participants. Interviews were conducted by both staff of africon, as well as a local research subcontractor.

Definitions of key terms

Throughout this report, the term `medical and laboratory equipment´ is used to refer to all types of products, services, or solutions used to improve people's health by preventing, diagnosing, monitoring, and treating disease. 'Medical equipment' in this report refers to devices and technologies used in a hospital setting while 'laboratory equipment' refers to devices used in a medical laboratory setting. They are categorized as follows:

Medical equipment

- *Therapeutic respiration apparatuses*
- *Catheters & cannula*
- *X-ray apparatuses including parts and accessories*
- *Furniture*
- *Syringes and needles*
- *MRI apparatuses*
- *Ultrasonic scanning apparatuses*
- *Orthopaedic or fracture appliances*
- *Sterilisers*
- *Breathing appliances and gas masks*
- *Artificial parts of the body*
- *Carriages for disabled persons*
- *Massage apparatuses and psychological aptitude-testing apparatuses*
- *Dental instruments and appliances*
- *Pacemakers*
- *Hearing aids*
- *Scintigraphy apparatuses*

Laboratory equipment

- *Optical radiations instruments and apparatuses (UV, visible, IR)*
- *Microtomes and parts and accessories thereof*
- *Physical or chemical analysis instruments and apparatuses for measuring or checking viscosity, porosity, expansion, surface tension or quantities of heat, sound or light*
- *Distilling or rectifying plants*
- *Spectrometers, spectrophotometers, and spectrographs using optical radiations (UV, visible light, IR)*
- *Centrifuges*
- *Sterilisers*
- *Heating equipment; for the heat treatment of materials by induction or dielectric loss, industrial or laboratory, other than furnaces and ovens*
- *Furnaces and ovens; electric, for industrial or laboratory use, other than those functioning by induction, dielectric loss or resistance heating*
- *Vacuum pumps*
- *Gas or smoke analysis apparatuses, for physical or chemical analysis*
- *Furnaces, ovens, and heating equipment*

- *Weighing balances*
- *Laboratory glassware*
- *Chromatographs and electrophoresis instruments*
- *Ultra-violet or infra-red lamps*
- *Compound and stereoscopic microscopes (including parts and accessories)*

Pre-export verification of conformity (PVoC): It is a conformity assessment procedure applied at the country of origin to ensure compliance of imported products with applicable destination country's standards.

Current healthcare expenditure: Includes healthcare goods and services that are consumed within a given year

Public health expenditure: Health expenditures that come from the domestic government.

Private health expenditure: Health expenditure from pooled resources with no government control, such as voluntary health insurance, and the direct payments for health by corporations (profit, non-for-profit and NGOs) and households

External health expenditure: Health expenditures that come from financial flows originating from outside the country, as measured by World bank.

Government health budget: Funds allocated to health functions from the government national budget.

2. KENYA

2.1. Country profile - Kenya

Geography

Kenya is situated on the African East Coast along the equator. It has a 1,420 km-long coastline along the Indian Ocean and also borders Tanzania, Uganda, South Sudan, Ethiopia, and Somalia. The natural landscape includes a coastal plain with sandy beaches, extensive semi-arid plateaus, fertile highlands, and the dramatic Rift Valley which cuts across Kenya from north to south. The climate ranges from hot and humid on the coast to cool and temperate in the highlands to semi-arid in its northern regions. Rainfall is unreliable throughout much of Kenya, which is aggravated by climate change, and less than one-fifth of the land is suitable for agriculture.

Social situation

Kenya has made major gains in social development, including reducing child mortality, achieving near universal primary school enrollment, and narrowing gender gaps in education. Kenya's Human Development Index (HDI) value for 2019 was 0.601[11], which puts it in the medium human development category, positioning it at 143 out of 189 countries and territories. Between 1990 and 2019, Kenya's HDI value increased by 24.7% from 0.482 to 0.601. During the same period, Kenya's life expectancy at birth increased by 9.3 years, mean years of schooling increased by 2.8 years, expected years of schooling increased by 2.3 years and Gross National Income (GNI) per capita increased by 37.1 percent.[12]

Economic situation

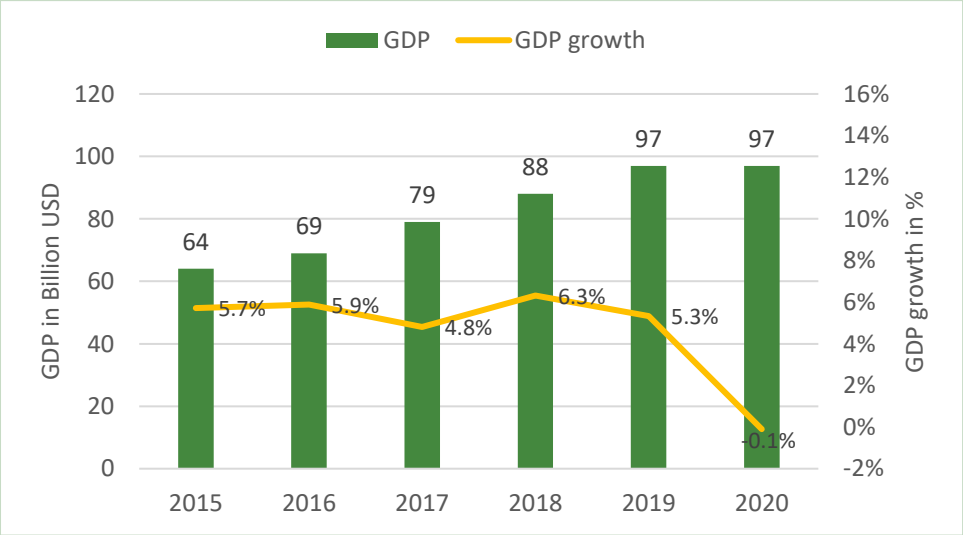


Figure 1: Kenya GDP and GDP growth rate (2015 -2019, Billion USD and % growth)[13]

The Kenyan economy, East Africa's largest, has experienced considerable growth in the past few years. Until the COVID-19 pandemic, Kenya was one of the fastest growing economies in Africa, with an annual average growth of 5.9% between 2010 and 2019[14]. This has been due to several factors including a reasonably well-educated labour force, a vital port that serves as an entry point for goods

[11] UNDP, Human Development Report Kenya 2020
[12] UNDP, Human Development Report Kenya 2020
[13] Kenya National Bureau of Statistics, Economic Survey 2020
[14] Kenya National Bureau of Statistics, Economic Survey 2020

destined for countries in Eastern and Central Africa, a vibrant tourism industry and above all, a government that is committed to implementing business reforms. With a GDP per capita of USD 1,816, Kenya is now classified as a lower-middle income country.

However, Kenya continues to face significant challenges in the areas of sustainable and inclusive economic growth, income inequality and corruption, which have been exacerbated by COVID-19's economic disruptions. Two-thirds of Kenyans live in poverty making below USD 3.20 per day. There is a persistently large gap between the rich and poor[15], with approximately 70 percent of Kenyan families chronically vulnerable due to poor nutrition, food insecurity, and preventable diseases. [16]

GDP composition

Agriculture sector is the mainstay of the Kenyan economy. It is the means of livelihood for over 80% of the population and accounts for 65 per cent of Kenya's export earnings.[17]

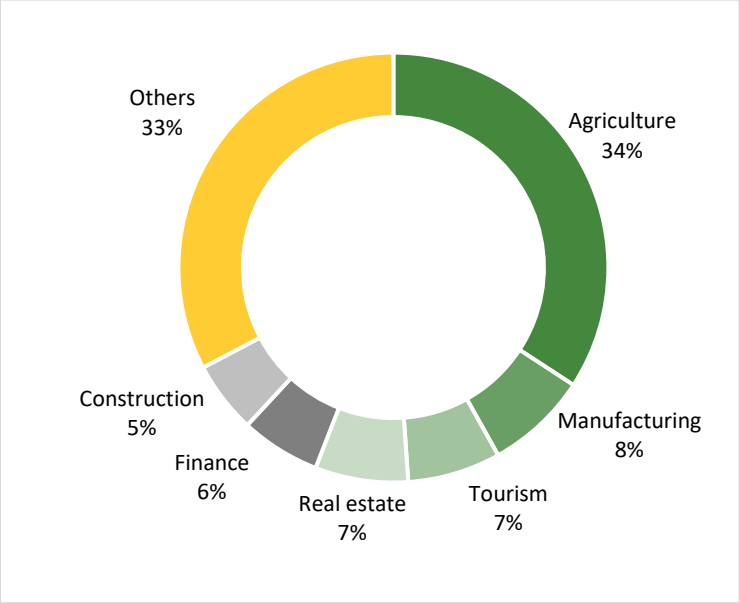


Figure 2: Kenya GDP composition (2019, % of total)[18]

The manufacturing sector in Kenya is mainly agro-based. It plays an important role in adding value to agricultural output by providing forward and backward linkages with the latter. However, there is a shift towards export-oriented manufacturing as Kenya's industrial policy aims to raise the share of the sector from 8% to 15% of GDP.[19]

Kenya's construction sector has been accelerating at a rapid pace. It is making a substantial contribution to the country's strong GDP growth figures on the back of major public works projects, as well as rising demand for mixed-use and residential developments.

Tourism is Kenya's leading foreign exchange earner. However, the sector was one of the hardest hit during the COVID-19 pandemic. Despite the lifting of travel restrictions, experts believe the

[15] World bank Gini index ranking
[16] USAID 2021
[17] IFAD 2019
[18] Kenya National Bureau of Statistics, Economic Survey 2020
[19] Ministry of Industrialization and Enterprise Development, Kenya Industrial Transformation Programme 2015

international tourist travel to Kenya could take up to four years to fully recover. The industry is therefore banking on domestic and regional tourism to make up for lost visitor numbers.[20]

COVID-19 impact

The Kenyan economy was hit hard by the COVID–19 pandemic as most economic activities slowed down due to containment measures. The restriction of movement slowed activities in transportation and storage, education, accommodation, and food services. Other sectors whose activities were affected, albeit at a lesser degree, include manufacturing, construction, wholesale, and retail trade. A weak global economy also negatively impacted on Kenya's exports, more so on horticultural products, and the tourism sector.

The economic and social disruptions brought about by the COVID-19 pandemic eroded progress in poverty reduction, increasing poverty by 4% or an additional 2 million people.[21]

Growth outlook

Most of the containment measures put in place in 2020 have since been relaxed and this is expected to accelerate economic recovery in 2021. International flights have resumed making it possible to export horticulture and enabling international tourists to travel to Kenya. The economy is projected to grow by 5.0% in 2021 and 5.9% in 2022.[22]

[20] Ministry of tourism Kenya, Impact of COVID-19 on the Travel and Tourism Industry 2020
[21] World bank 2021 2021
[22] AfDB, Kenya Economic outlook 2020

2.2 Overview on the health sector - Kenya

2.2.1 Healthcare system - Kenya

In 2010, Kenya approved a new constitution through a referendum that marked the beginning of devolution. Under the new constitution, the responsibility of public health service delivery for primary and secondary health services were devolved to 47 newly created counties, while national government retained policy and regulatory functions. In 2013, the new constitution came into effect and the changes in roles and responsibilities from the national to the county level became a reality. The goal of devolution in healthcare was to enhance equity in resource allocation, thereby improving service delivery for the majority of Kenyans, especially those residing in rural areas.[23]

Under the devolved system, the national government's functions were limited to policymaking, financing, quality assurance and standards, monitoring and evaluation, education, national referral hospitals, national laboratories, management of port health, national healthcare agencies such as National Insurance Hospital Fund (NHIF), Kenya Medical Supply Agency (KEMSA), Kenya Medical Research Institute (KEMRI) and disease control programmes, like tuberculosis and HIV. The county governments became responsible for management of county health facilities, ambulance services, promotion of primary healthcare, disease surveillance and response, public health and sanitation, disaster management, veterinary services, and waste disposal.

Health infrastructure

Kenya has a total of total of 13,435 registered health facilities as of September 2021. 6,183 of these facilities are government owned, 5,821 are private and for-profit while 1,431 are faith-based not-for profit.[24]

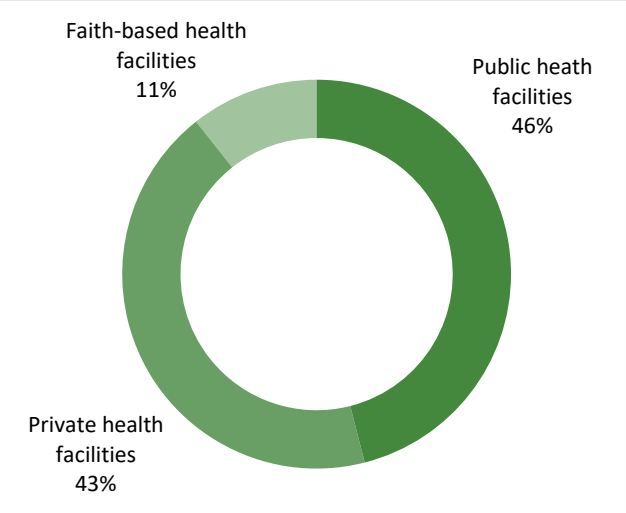


Figure 3: Ownership of health facilities in Kenya (2021, % of total)[25]

The Kenyan healthcare system is hierarchical and is organized around six levels of care. The first level starts at the community level and is mainly focused on promotive health and treatment of minor ailments. The second and third level provide primary care services and include dispensaries and health centres that offer basic outpatient care, maternity, and minor surgical services. The fourth and fifth levels provide secondary care services and include county health facilities that offer a broad

[23] Kenya school of government, Kenya devolution, Working paper No.1 2015
[24] Kenya Master Health Facility List (KMHFL) 2021
[25] Kenya Master Health Facility List (KMHFL) 2021

spectrum of treatment. The highest level of care forms the tertiary level, which offers specialized care besides training to health workers.

The

Level of health facility	Number of facilities
National Referral hospitals (Level 6)	6
County referral hospitals (Level 5)	21
County hospital (Level 4)	867
Health centres (Level 3)	2,052
Community health centres and dispensaries (Level 1 & 2)	10,489
Total	**13,435**
Ratio per 1,000 population	**0.28**

national health facility density in 2021 stood at 0.28 per 1,000 population, which is above WHOs recommended target of 0.2 per 1,000.[26]

Table 1: Health facilities by level in Kenya (2021)[27]

Health workforce

Kenya is experiencing a health workforce shortage. In 2018, the national health workforce density of doctors, nurses and midwives stood at 1.06 per 1,000 population[28], which was below the minimum threshold of 4.45 per 1,000 population recommended by WHO.[29]

The shortage of health workers is mainly due to poor pay and brain drain. Health workers particularly those in the private sector are overworked and underpaid which is a huge demotivator, as evidenced by frequent strikes. These poor working conditions results in health workers emigrating from Kenya to developed countries or internally from rural to urban areas, resulting in critical shortages in some regions of the country. It is also not uncommon for medical doctors to work in public health facilities in the morning, and at their private practices in the afternoon to substitute their income. This practice is commonly referred to as `moonlighting´.

Type of health worker	Number of health workers	Ratio per 1,000 population
Medical Doctor	3,083	0.06
Nurses (including midwives)	51,390	1.0
Total	**54,473**	**1.06**

Table 2: Health workforce in Kenya (2018)[30]

2.2.2 Healthcare expenditure - Kenya

Healthcare spending in Kenya comes from three main sources – public, private, and external sources. Public and private spending account for the largest share of health expenditure. The high level of private spending is due to the large uninsured population, which means the majority of people pays

[26] Kenya Master Health Facility List (KMHFL) 2021
[27] Kenya Master Health Facility List (KMHFL) 2021
[28] Kenya Harmonized Health Facility Assessment (KHFA) 2018/2019
[29] WHO, Health workforce requirements for UHC and the SDGs 2016
[30] Kenya Harmonized Health Facility Assessment (KHFA) 2018/2019

out-of-pocket for healthcare services. However, unlike its neighbours, Kenya has a lower dependency on external sources for healthcare spending. This is because Kenya officially became a low-middle income country in 2014 which made it ineligible for certain donor assistance programmes.

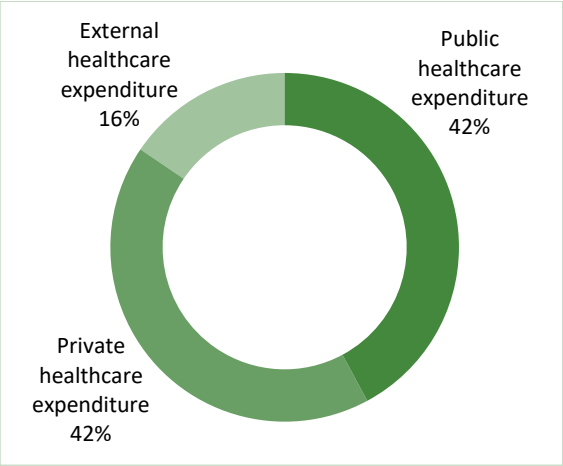


Figure 4:Kenya Health expenditure by source (2018, % of total)[31]

Health expenditure per capita in Kenya has seen a steady increase from USD 56 in 2011 to USD 88 in 2018. The spending has however not kept up with GDP. The health expenditure as a ratio of GDP has declined marginally from 5.8% in 2011 to 5.2% in 2018.

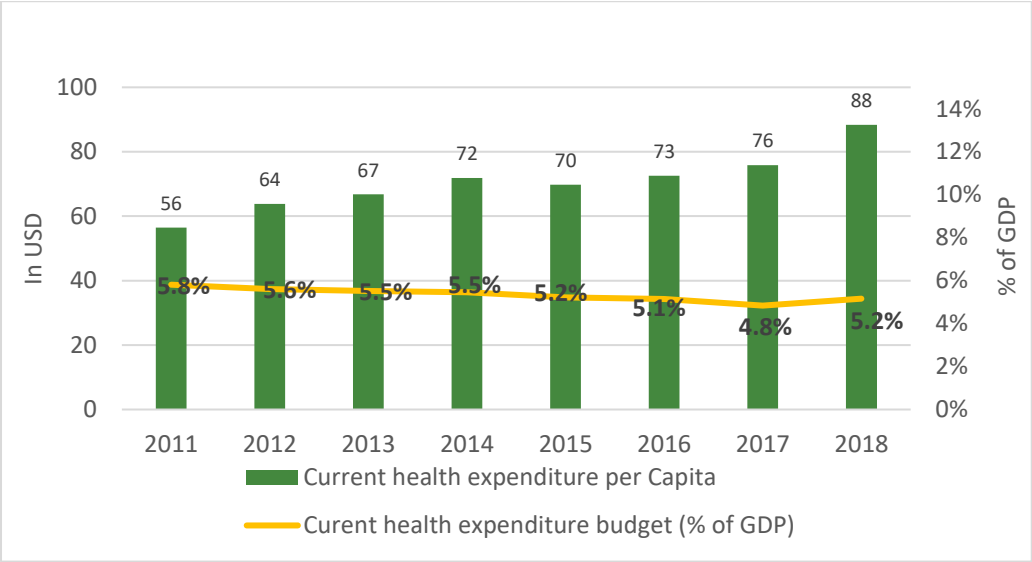


Figure 5: Kenya current healthcare expenditure (2011 - 2018, Per capita and as % of GDP)[32]

Health sector budgetary allocation by the national government continues to see a steady increase as the government strives to achieve universal healthcare. The 2020/21 national health budget increased by 10.3% to USD 1.06 billion compared to USD 966 million in 2019/20[33]. The 2020/21 national budget was prepared at a time when the country was grappling with the health, social and economic impacts of the COVID-19 pandemic. As a result, budgets were slashed for most other ministries and directed towards the health sector to curb the escalation of COVID-19 cases. This

[31] World bank, 2021
[32] World bank, 2021
[33] Kenya national treasury, Budget book 2020/21

resulted in the health budget as a share of the total national budget increasing from 5.5% in 2019/20 to 6.5% in 2020/21.[34]

Increased health budgetary allocation is expected to benefit medical and laboratory equipment suppliers especially as the government prioritizes universal healthcare which, among other things will also involves equipping of health facilities across the country with critical medical equipment.[35]

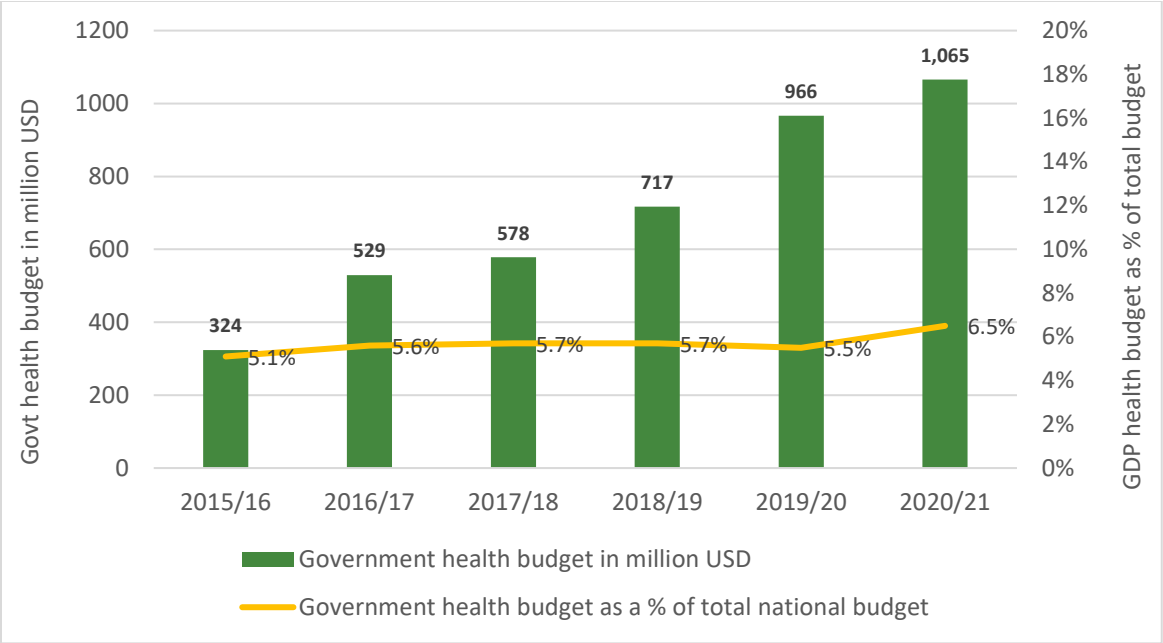


Figure 6: Kenya national health budget and its share of total national budget (2015 – 2021, million USD and % growth)[36]

2.2.3 Disease burden and trends - Kenya

	Top 10 diseases causing death 2009		Top 10 diseases causing death 2019	% change in deaths 2009-2019
1	HIV/AIDS	1	HIV/AIDS	-41.5%
2	Diarrheal diseases	2	Lower respiratory Infections	-4.9%
3	Lower respiratory Infections	3	Diarrheal diseases	-30.1%
4	Neonatal disorders	4	Neonatal disorders	-11.3%
5	Tuberculosis	5	Stroke	27.7%
6	Stroke	6	Tuberculosis	-4.5%
7	Cirrhosis	7	Ischemic heart diseases	36.8%
8	Ischemic heart diseases	8	Cirrhosis	21.4%
9	Malaria	9	Malaria	35.0%
10	Menegitis	10	Diabetes	39.5%
12	Diabetes	17	Menegitis	-15.3%

[34] Kenya national treasury, Budget book 2020/21
[35] Kenya National Treasury, Budget highlights 2021
[36] Kenya National Treasury, Budget book 2020/21

Table 3: Top 10 diseases causing deaths in Kenya (2009, 2019, % change)[37]

Kenya is experiencing an epidemiological transition in its diseases burden from infectious to non-communicable diseases (NCDs) resulting in a double burden of disease. In 2018, non-communicable diseases accounted for 27% of the total deaths and over 50% of total hospital admissions.[38] The rise in the burden of NCDs is associated with demographic and social changes such as globalisation, urbanization, aging population, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption.

Between 2009 and 2019, number of deaths related to non-communicable and lifestyle-related diseases like diabetes, stroke, ischemic heart diseases and cirrhosis were on the rise, while deaths related to communicable, maternal, neonatal, and nutritional diseases recorded a decline.[39]

Although significant progress has been made towards containing the threat of communicable diseases such as HIV/AIDS, malaria and tuberculosis, their burden on the health sector is still significant. HIV/AIDS was still Kenya's largest killer disease in 2019, despite a decline of 41.5% between 2009 and 2019. Malaria-related deaths increased by 35% during the same period, despite heavy resources being deployed by donors to fight the disease. Tuberculosis only recorded a slight decline of -4.5% and dropped from position 5 to 6 during the same period.

The epidemiological transition from infectious to non-communicable diseases is expected to result in an increasing demand for new medical equipment and technology for diagnosing and managing emerging chronic diseases such as cardiovascular diseases and diabetes.

[37] IHME, 2019
[38] CDC, Kenya Annual Report 2018
[39] IHME 2019

2.3. Medical and laboratory equipment landscape - Kenya

2.3.1. Medical equipment and technology value chain - Kenya

Almost all medical devices used in Kenya are imported with domestic production being primarily focused on basic consumable items. The value chain differs from public to private facilities.

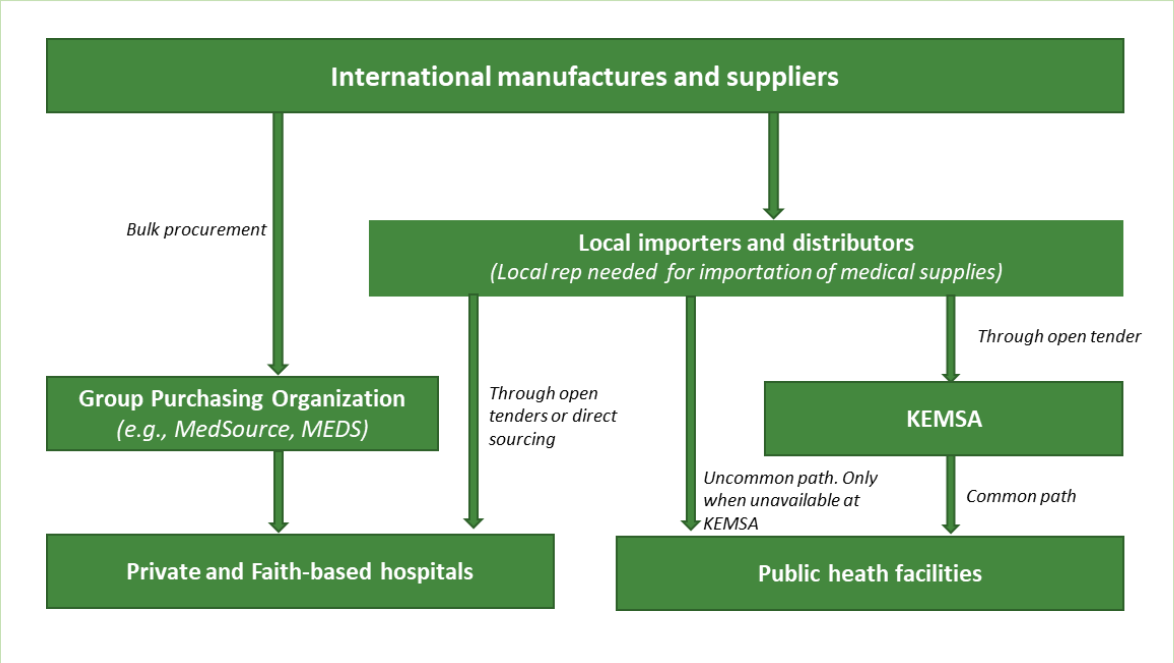


Figure 7: Kenya medical and laboratory equipment value chain (2021)[40]

Public Sector

In the public sector, procurement of medical supplies is centralized through the Kenya Medical Supplies Authority (KEMSA), which is the lead government supply chain agent mandated with procuring, warehousing, and distributing medical commodities to all public health facilities in the country. KEMSA has a priority over other private distributors when it comes to selling to public health facilities. By law, public health facilities are obligated to first purchase from KEMSA and only when unavailable can they source from private distributors.

KEMSA does not receive direct funding from the government but relies on a revolving fund from purchase payments. Under this not-for-profit self-sustaining commercial business model, the health facilities order and pay for their medical commodities and the funds acquired from these sales goes towards replenishing stock.

Procurement of capital-intensive equipment does not always follow the KEMSA value chain. Since capital intensive medical and laboratory equipment is rarely procured in bulk, procurement is done on a needs basis and can be sourced directly from an independent distributor either by the hospitals (for national and referral hospitals) or by the county government for county hospitals and other facilities under its mandate.

Private sector

[40] africon research (2021)

In the private sector, procurement of medical and laboratory equipment is done directly through independent distributors or group purchasing organizations. The two main group purchasing organizations operating in Kenya are Mission for Essential Drugs and Supplies (MEDS), and MedSource. MEDS is a large-scale, bulk procurer of medicines and health products mainly targeted towards faith-based and commercially operated private hospitals while MedSource is a member driven organization open to not only health facilities but also pharmacies interested in leveraging the combined purchasing power of members to negotiate favourable contract pricing from suppliers. Capital intensive medical and laboratory equipment, similar to public hospitals are procured directly from distributors on an as needed basis.

2.3.2. Import trends of medical and laboratory equipment - Kenya

Import of medical equipment has seen some ups and downs over the past decade. There was a steady increase between 2011 and 2014 followed by a sharp spike in 2015. This was triggered by the managed equipment services (MES) project, a national government programme launched in 2015 meant to equip two hospitals in every county with leased state-of-the-art medical equipment. Leasing was seen as an alternative healthcare financing option to scale up health infrastructure for provision of specialized medical care. Some of the firms involved in this project included China's Shenzhen Mindray, India's Esteem Industries, General Electric, and Philips.

Despite the project being plagued by corruption scandals regarding opaque procurement processes and inflated costs, over 60 hospitals have now been equipped with equipment ranging from X-ray, ultrasound, dialysis machines as well as MRI and CT scanners[41]. For this reason, import of these machines is expected to decline significantly over the next 10 years especially in the public sector. However, other medical equipment and consumables are expected to maintain moderate growth similar to that of pre-MES (2011-2014) level of 3.6% CAGR.

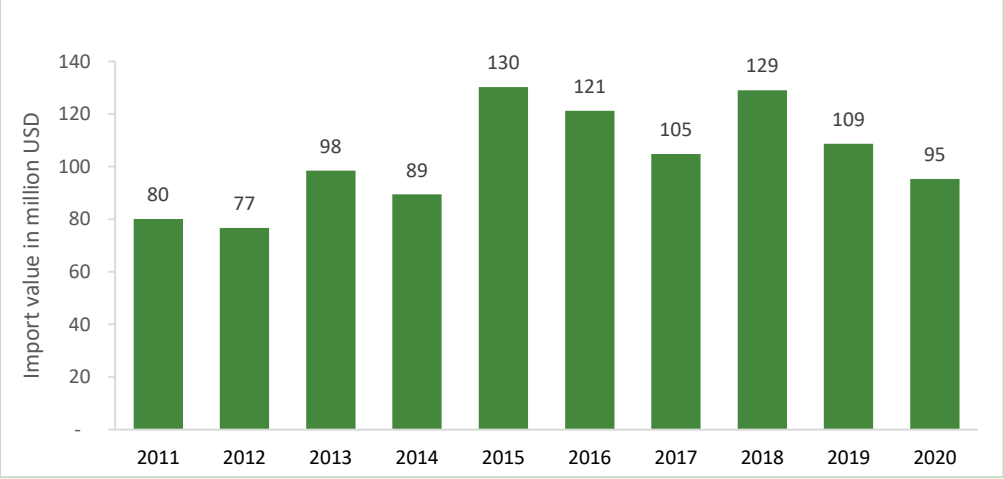


Figure 8: Kenya import value of medical equipment (2011-2020, million USD)[42]

Laboratory equipment imports have been relatively flat over the past decade with a 22.4% decline recorded in 2020 compared to 2019 due to economic disruption brought about by the COVID-19 pandemic. However, this is expected to recover to pre-pandemic levels as more businesses resume normal operations in the second half of 2021. Growth in the next five years is expected to go back to pre-pandemic levels of 3.2% CAGR.

[41] Standard media
[42] UN Comtrade, 2021

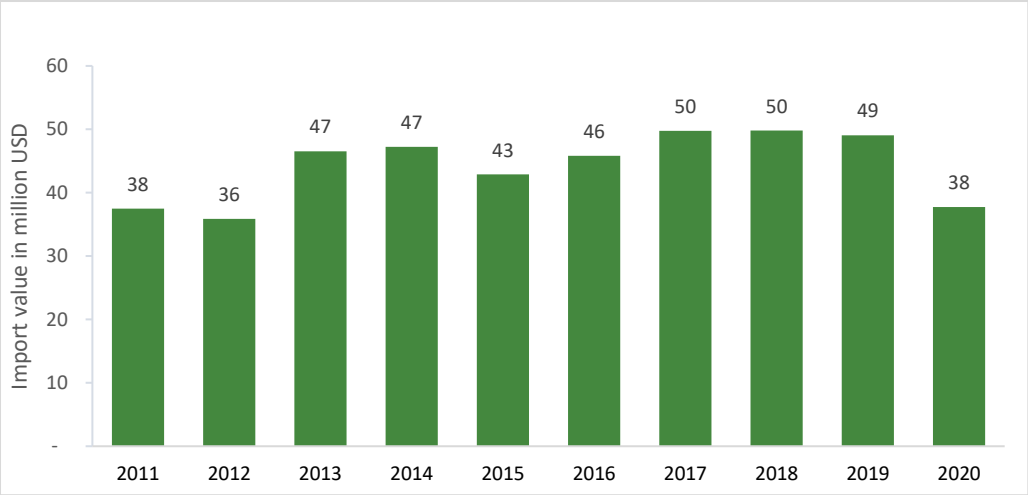


Figure 9: Kenya import value of laboratory equipment (2011-2020, million USD)[43]

Although COVID-19 brought to a halt large capital investment in medical equipment, it did lead to a high demand for therapeutic respiratory apparatuses in 2020 resulting in an all-time high import of USD 13.5 million compared to USD 4.7 million in 2019. Respiratory problems were the main complication faced by COVID-19 patients and therefore breathing aid devices were needed to support patients who had acute respiratory problem due to pneumonia associated with or subsequent to COVID-19. However, with COVID-19 cases declining significantly in 2021, imports are expected to drop below pre-pandemic levels as most hospitals will be left with excess capacity built up during the height of the pandemic.

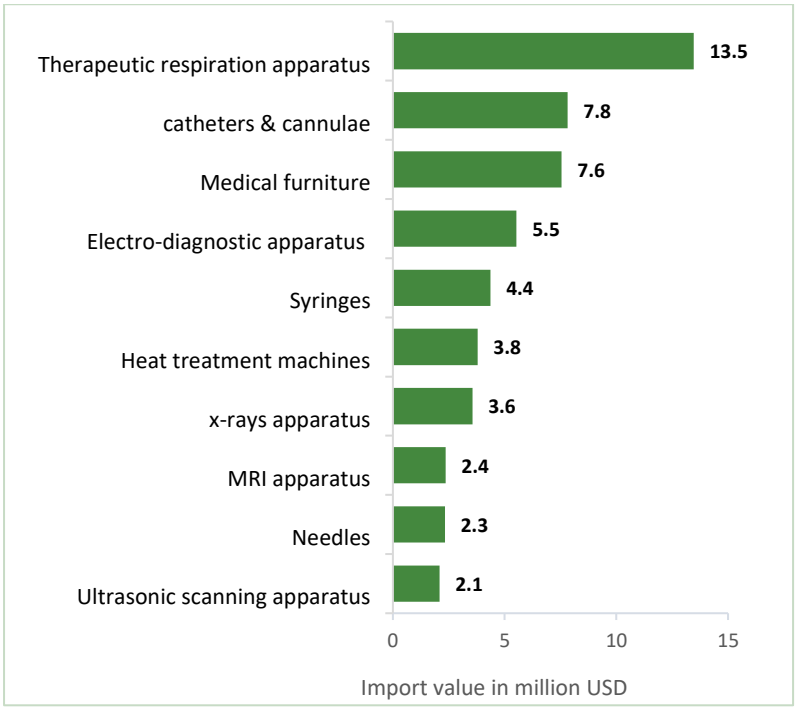


Figure 10: Kenya top 10 medical equipment imports (2020, million USD)[44]

[43] UN Comtrade, 2021
[44] UN Comtrade, 2021

Optical radiation apparatuses, heat treatment machines and microtomes were the top three laboratory equipment imports in 2020. This has been consistent with past years as well indicating that demand was stable despite COVID-19.

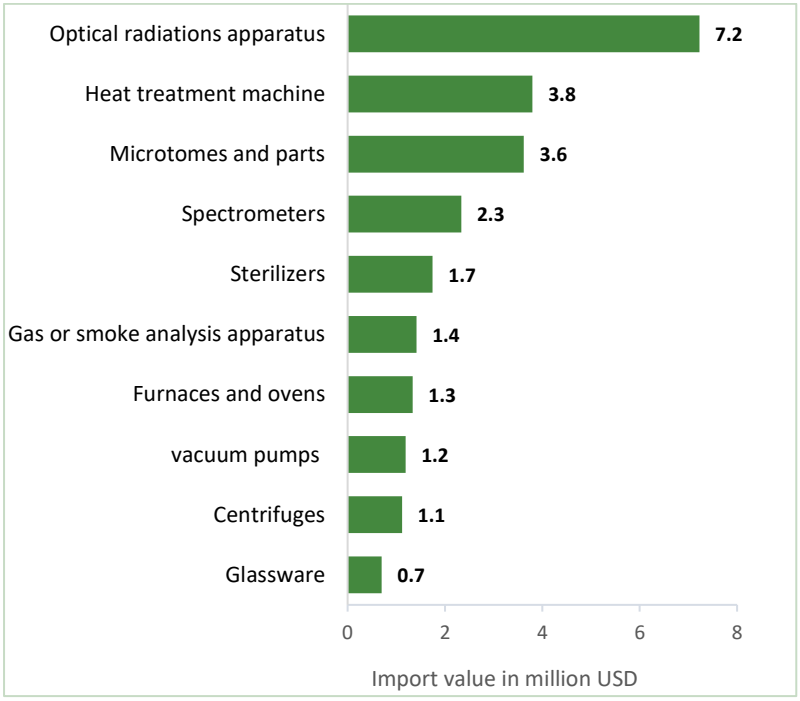


Figure 11: Kenya top 10 laboratory equipment imports (2020, million USD)[45]

China is by far the leading source of imports for medical equipment with about 30% of market share. However, western countries combined hold a market share of about 53% of medical equipment imports in Kenya, thus are collectively the main source.

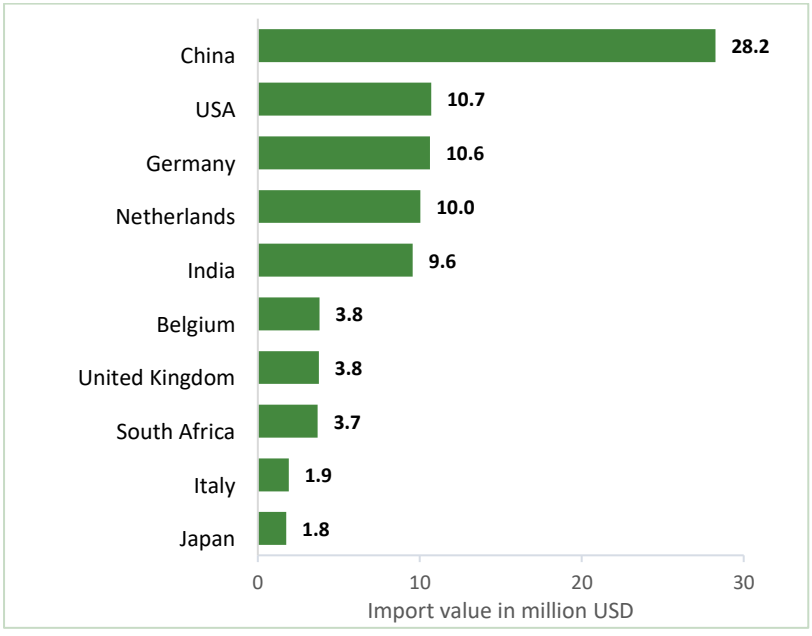


Figure 12: Origin of medical equipment imports in Kenya (2020, million USD)[46]

[45] UN Comtrade, 2021

China is also Kenya's second most important supplier in the laboratory equipment segment with a market share of 20%. The leading exporting country however is Germany with a market share of 21%. Western countries combined account for 56% laboratory equipment imports, thus are collectively the main source. Despite China making a lot of progress in grabbing market share in the laboratory equipment market, the fastest growing sources of imports between 2011 and 2020 were South Korea and Belgium with increases if 380% and 366% respectively. China on the other hand grew its exports by 90% while Germany grew by 29% during the same period.

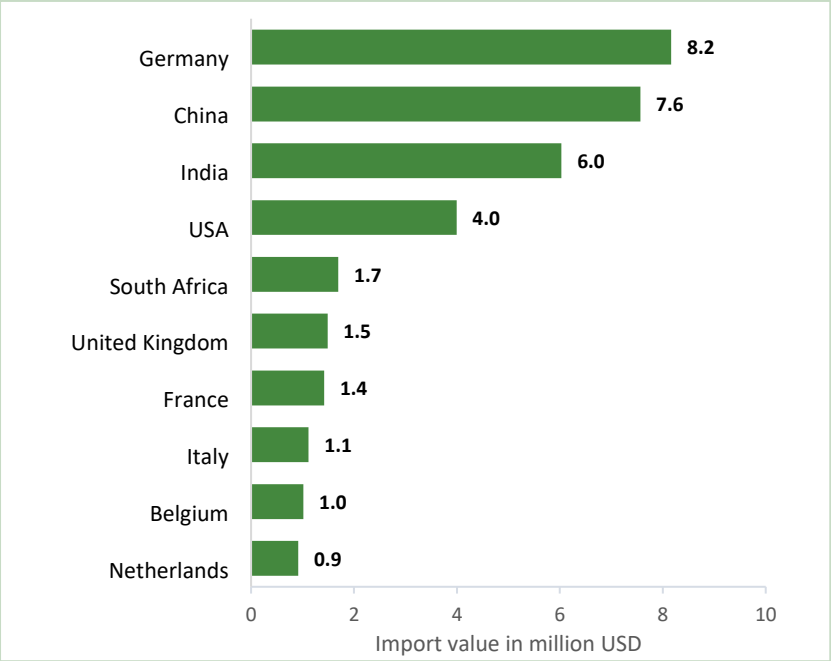


Figure 13: Origin of laboratory equipment imports in Kenya (2020, million USD) [47]

[46] UN Comtrade, 2021
[47] UN Comtrade, 2021

2.3.3. Medical and laboratory equipment investment decision-making process - Kenya

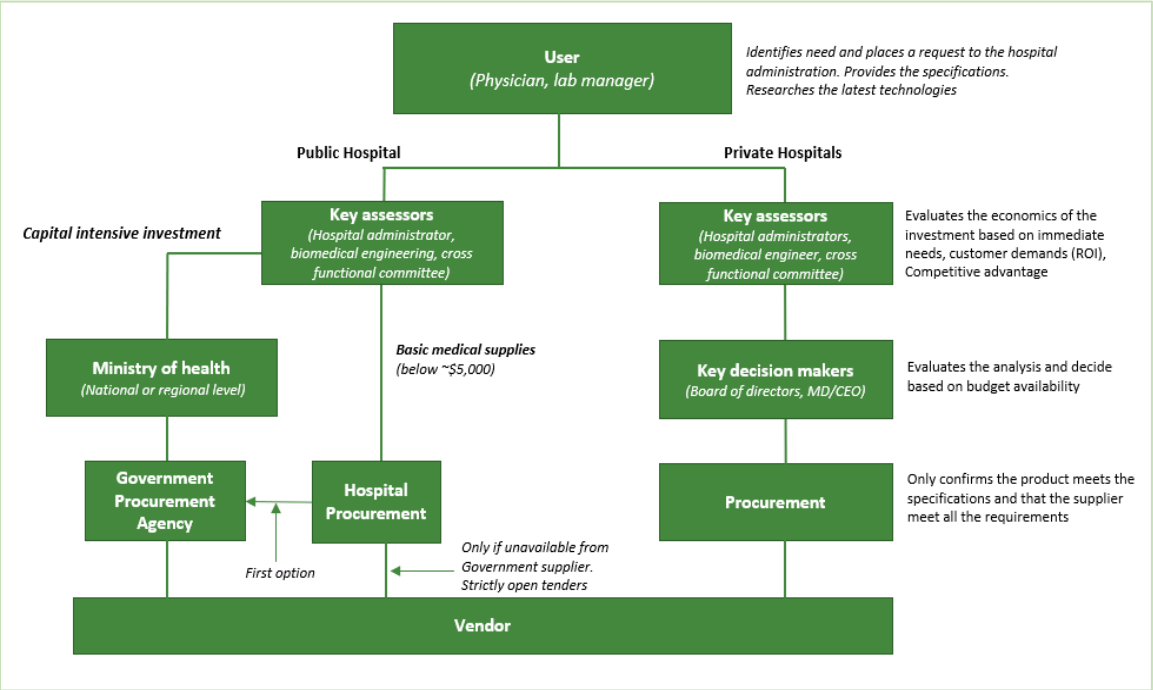


Figure 14: Medical and laboratory equipment investment-decision making process in Kenya (2021)[48]

Capital investment decisions on medical technology is usually a participative process. Various stakeholders, including product users, hospital administrators, accounting officers, procurement officers, and hospital management have their input into the final decisions. The process typically starts with the user, in most cases lab manager or physicians putting forward a request for new equipment. The user is tasked with providing clinical and business relevant information to justify investment. The stakeholders will evaluate the purchase option based on key metrics that may include return on investment, immediate need, hospitals technical capacity, as well as the competitive edge the equipment would provide against competitors.

Procurement in the public sector is challenging due to bureaucratic delays and budget constraints. County governments have huge budgetary constraints with significant proportions of their annual allocations going to recurrent expenditure, particularly personnel emoluments. Very little budgetary space is left for capital investment in medical and laboratory equipment. The flow of funds to facilitate the procurement of medical equipment at both national and county level is also unpredictable.

Source of information on new medical technology

Based on the research conducted by africon, direct contact with vendors was found to be the primary way hospitals and labs learnt about new medical technology. Medical and laboratory equipment suppliers typically have agents or distributors. These are responsible for reaching out and educating potential customers on the latest technologies. Another popular way hospitals learn about new technologies is through recommendation from their professional circle. Online resources were also a common option but lacked the face-to-face interaction with the seller and therefore was

[48] africon research 2021

considered less effective. Conferences and trade shows were least popular with the majority of health practitioners never having attended a single event due to the financial and time investment needed.

Purchasing criteria

Based on the research conducted by africon, price and quality were the primary factors considered during product selection. All other factors were considered secondary. The public sector has a strict open tendering process and therefore does not consider factors not outlined in the tender document. Private sector procurement is much more flexible with brand reputation and familiarity playing a key role after price and quality. Health players are less willing to take risks on unknown and unproven brands. Purchasing terms especially financing is also a big factor especially for lab testing equipment where placement contracts are standard. With placement contracts, manufacturers (or their distributor) provide laboratory equipment at no cost to a laboratory, which in turn is obligated to purchase a minimum amount of reagents, usually per quarter, at a pre-determined price from the manufacturer (or distributor) of the equipment. German brands are considered high quality and therefore highly preferred.

2.3.4. Medical and laboratory equipment regulation - Kenya

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority established under the Pharmacy and Poisons Act, Chapter 244, the Laws of Kenya mandated to regulate the Practice of Pharmacy and the Trade in Drugs, Poisons, Medical Products and Health Technologies.

According to PPB, a medical device are defined as any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
    i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
    ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
    iii. investigation, replacement, modification, or support of the anatomy of a physiological process;
    iv. supporting or sustaining life;
    v. control of conception;
    vi. disinfection of medical devices;
    vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;
b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

Import process

Any foreign manufacturer looking to market their products in Kenya must first designate a local authorized representative (LAR). The LAR must have written evidence confirming that they are acting with the authorization from the manufacturer. The responsibility of the LAR is to ensure regulatory compliance and serve as the central communication pathway with the PPB.

For any medical and laboratory equipment to be imported into Kenya, a Certificate of Conformity (CoC) must first be obtained from the Kenya Bureau of Standards (KEBS). KEBS has put in place a Pre-Export Verification of Conformity (PVoC) process whereby the conformity assessment is conducted at

the country of origin through a KEBS appointed agent who include SGS, Intertek and Bureau Veritas, after which a certificate of conformity (CoC) is awarded for products meeting the requirements.

All medical devices also have to be registered by PPB before being imported into Kenya. An application for registration of a medical device should be submitted by the authorized local agent of the manufacturer. Documents to be submitted in during the registration stage include ISO certification, CE (European Conformity) certification, regulatory approval certificate from country of origin, certificate of analysis, product packaging and instructions for use of the product.

After registering the medical device and obtaining a CoC, the importer can now apply for an import Permits from Pharmacy and Poisons Board (PPB) through the Kenya National Single Window Electronic (Kentrade) System. KEBS will make the CoC data available to PPB through Kentrade. The importer will need to produce the import permit and CoC for clearance of cargo at the port of entry.

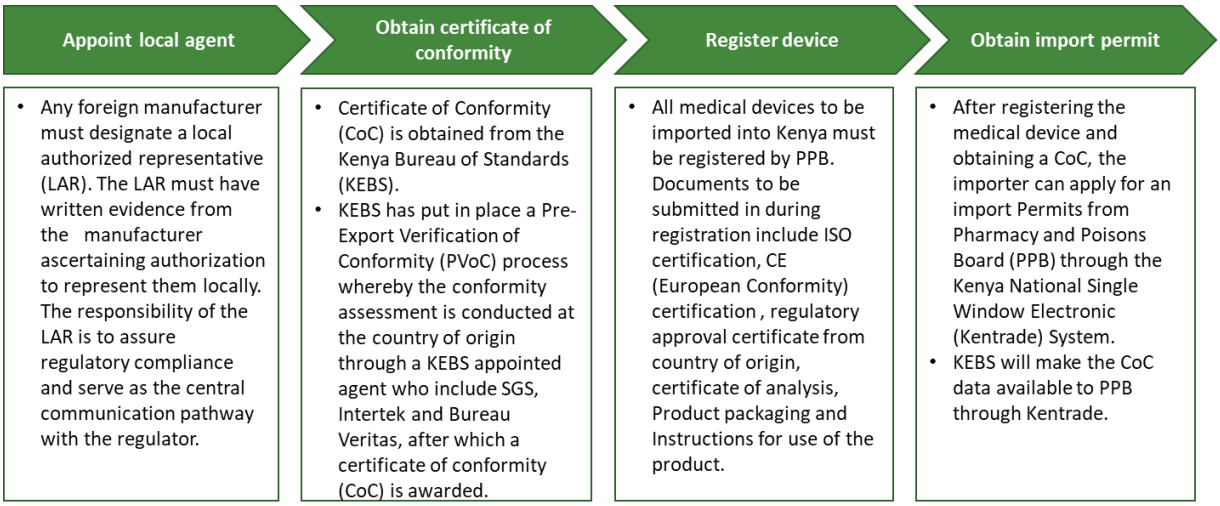


Figure 15: Kenya medical and laboratory equipment import process (2021)[49]

[49] africon research 2021

2.3.5. E-health in Kenya

The state of E-health in Kenya

Despite the rapid growth of ICT in Kenya, high mobile penetration and the clear benefits of e-health adoption, healthcare players are yet to adopt e-health at a large scale. This is especially the case in the public sector where manual record keeping is still a common occurrence. A survey conducted by africon among health facilities in Kenya found that private hospitals are ahead when it comes to e-health adoption, mainly for patients record keeping. Other benefits such as telemedicine and electronic procurement systems are yet to be leveraged fully. Public hospitals on the other hand were lacking when it comes to e-health adoption, except for a few large national and county hospitals.

E-health adoption challenges

Adoption of e-health does not come without its limitations with the largest barrier being the cost of acquisition. To implement an e-health system, the upfront cost not only includes the system itself but also all the supporting infrastructure that ensures it runs smoothly including computers, stable internet, servers, and file storage options such as cloud. Other limitations include low literacy rate, inadequate technical expertise, unreliable power supply and limited funding. According to the ministry of health, most eHealth projects implemented in Kenya are mainly funded by development partners and Non-Governmental Organizations (NGOs) raising the issue of ownership and sustainability.

E-health policies

One of the pillars of Kenya's Vision 2030 is providing the highest attainable standard of healthcare to all Kenyans. To fulfil this mandate, the Ministry of Health developed the Kenya Health Policy (2014-2030). The policy objectives include planning, designing, and installing ICT infrastructure, as well as software for the management and delivery of essential healthcare. The Ministry of Health has prioritized the need to develop and operationalize a comprehensive national e-health policy that clearly outlines the strategic direction on the use of ICTs in the healthcare sector. For this reason, the Ministry of Health developed the Kenya National eHealth Policy 2016–2030.

The Kenya National eHealth Policy 2016–2030 strategic priorities include standardization of e-health hardware and software, integrating e-health into the existing healthcare systems and a participatory approach in the design, development and implementation of e-health interventions, including leveraging public-private partnerships, which may expedite e-health adoption.[50]

2.3.6. E-learning in Kenya

Health training landscape

Many actors are involved in the training of health workers in Kenya including, among others, the Kenya Medical College training system, public, private and faith-based universities, training colleges, regulatory bodies, placement sites, international bodies, and donor organizations. [51] Kenya has 11 medical and dental schools[52] and 121 nursing/midwifery training institutions.[53] Kenya Medical Training College (KMTC) is the main institution tasked with training health professionals in Kenya

[50] Ministry of health, Kenya National eHealth Policy 2016–2030
[51] Ministry of health, Kenya Health Workforce Report - 2019
[52] Nursing Council of Kenya
[53] Kenya Medical Practitioners and Dentists Council

producing over 12,000 graduates every year, with over 90 of them being certificate and diploma graduates.[54] All other public and private health training institutions combine for an average of 4,00 graduates annually.[55]

Health training is not limited to the classroom, but majority of programmes require practical training as part of their curriculum. The level of practical curriculum depends on the type of training. Certificate courses have the largest portion of their curriculum held as practical training at 70% of the curriculum, diploma at 50% while advanced programmes, including graduate diploma and undergraduate degrees, having the least amount of practical training of about 30% of their respective curriculum.

E-learning in health training

E-learning is yet to be widely adopted in health training, but the COVID-19 pandemic left majority of training institutions scrambling to incorporate e-learning to their programmes. In 2007, Kenyan higher education institutions were compelled by the government to introduce e-learning under the country's Vision 2030 strategic plan. The idea was to increase the number of people that could access higher education, given that demand for space at higher education institutions far exceeded supply at that time. The government also wanted to ensure higher education institutions were keeping up with technological innovation.

However, according to a survey conducted by africon among health training institutions in Kenya, the roll out of e-learning has not been without its challenges. All the 3 institutions seemed to face similar issues including instructors who do not have the skills to teach online, scarce electronic content, a lack of internet connectivity, limited access to computers, students with limited computer literacy, and frequent electricity blackouts. Additionally, a recent survey carried out across 12 public and private universities in Kenya also showed that students preferred face-to-face or blended methods of teaching and learning compared to e-learning.[56]

The same institutions however reported the benefit of being able to teach larger classes with fewer instructors. With a shortage of qualified instructors affecting most health training institutions, e-learning made it possible for one instructor to hold sessions with students from multiple campuses at the same time.

[54] Kenya National Bureau of Statistics, Economic survey 2020
[55] Kenya National Bureau of Statistics, Economic survey 2020
[56] George L. Makokha (2016), Status of E-Learning in public universities in Kenya

3. Uganda

3.1. Country profile - Uganda

Geography

Uganda is a landlocked country situated along the equator. It borders South Sudan to the north, the Democratic Republic of the Congo to the west, Kenya to the east, and both Rwanda and Tanzania to the south. The southern part of the country includes a substantial portion of Lake Victoria, shared with Kenya and Tanzania. Uganda lies within the Nile basin and has a varied but generally a moderate equatorial climate. The country's landscapes vary from volcanic ranges to savannas and swamps.

Social situation

Uganda's Human Capital Index (HCI) is low. Education completion rate is low and dropout rates are high. According to the World Bank, a child who starts schooling at the age of 4 is only expected to complete 6.8 years of school by its 18th birthday, compared to the Sub-Saharan average of 8.3. Additionally, 83% of 10-year-olds cannot read and understand a simple text by the end of primary school. This is a higher proportion than in the Sub-Saharan average of 80%.[57]

In addition, infant mortality rate is high. Under-five mortality rate stood at 45.8 per 1000 live births in 2019.[58] Malnutrition is high and stunting affects 29% of children in Uganda aged 5 years and below. Projected to grow at 5.2%, Uganda's population is expected to reach 100 million by 2050.The annual rate of urbanization, which is the rate at which the population shifts from rural to urban areas stood at 5.4% in 2020, which was among the highest rate in the world. The urban population is expected to increase from 11.4 million in 2020 to 22 million by 2040.[59], which would make Uganda one of the most urbanised countries in Africa.

Economic situation

Uganda's economy has been on a strong growth trajectory since 2017, but this was brought to a halt by the COVID-19 pandemic. Uganda was heavily hit resulting in a GDP decline of 0.5% in 2020, after growing 7.5% in 2019.[60] Economic activity stalled during the latter part of 2020 due to a domestic lockdown that lasted more than four months, border closures for all but essential cargo, and the spill over effects of disruptions to global demand and supply chains. This resulted in a sharp contraction in public investment and deceleration in private consumption, which hit the industrial and service sectors hard, particularly the informal service sector.

[57] World Bank, Country Overview Uganda 2021
[58] UNICEF
[59] World Bank, Country Overview Uganda 2021
[60] AfDB, Uganda Economic Outlook 2021

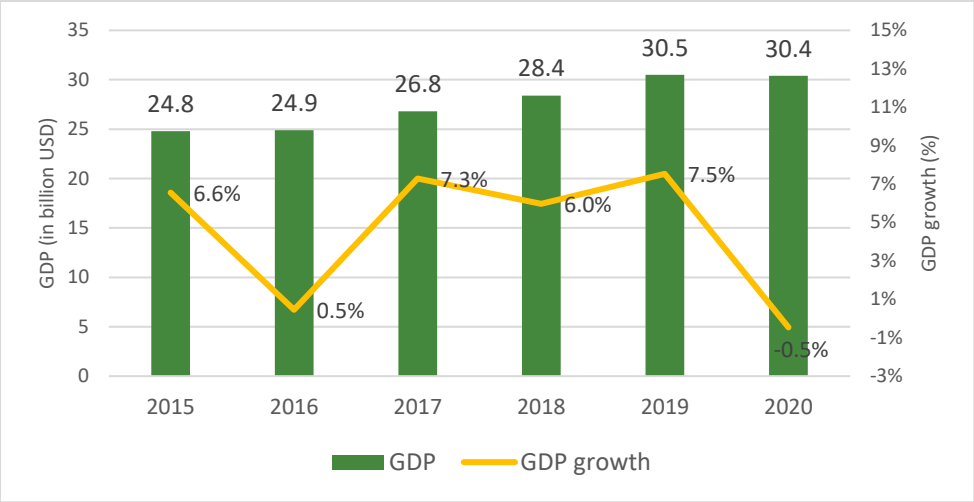


Figure 16: Uganda GDP and GDP growth rate (2015-2020, billion USD and % growth)[61]

GDP composition

Uganda's economy is divided into three major sectors - agriculture, industry, and services. Contributing 46% of the country's GDP, the services sector continues to see the highest growth. It is followed by industry, with a contribution of 28% and trailed by agriculture, which contributes 26% of GDP.[62]

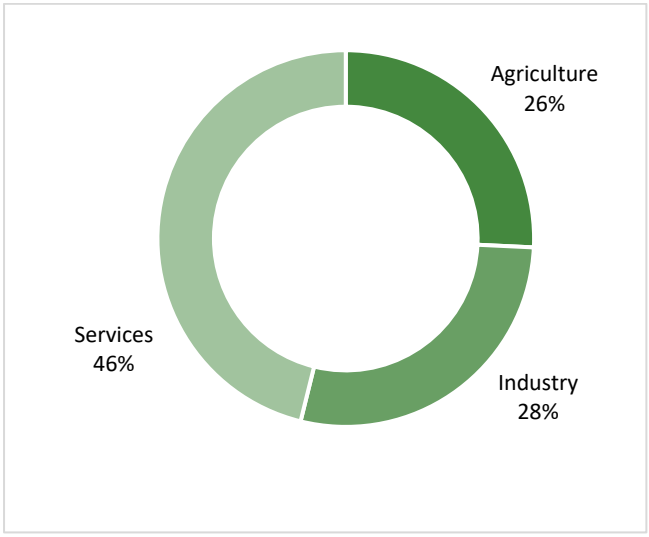


Figure 17: Uganda GDP composition (2019, % of total)[63]

Uganda heavily relies on agriculture and low value-added industrial output for job creation, public finance, and exports. Despite only accounting for 26% of GDP, agriculture employs over 80% of Uganda's population. [64] This is mainly because the agriculture sector is primarily based on subsistence and smallholder production.

[61] AfDB, Uganda Economic Outlook 2021
[62] Uganda Bureau of Statistics, Statistical abstract 2020
[63] Uganda Bureau of Statistics, Statistical abstract 2020
[64] Overseas Development Institute (ODI), Industrial development in Uganda 2019

The industrial sector in Uganda is underdeveloped and dominated by agro-processing, food and beverages, household products, construction materials and fast-moving consumer goods. Most of these industries consist of small and medium sized enterprises concentrated in the Kampala and Central regions. Most of the manufactured products are aimed at domestic consumption. Exports are limited to the regional markets, mainly due to the landlocked location of the country.

COVID-19 impact

The socio-economic impact of COVID-19 disproportionately affected the poorest sections of society. In Uganda, the informal sector is which makes up 50% of the economy and employs 98% of the working age labour force. This sector was the most affected by COVID-19 restrictions. It is estimated that about 23% of those in the informal sector lost 100% of their daily income during and after the lockdown.[65] Those that remained afloat are facing worse credit and liquidity constraints than they did prior to the pandemic.

Outlook

Uganda has seen a rebound in business activity following gradual easing of the lockdown measures and return to normal trading activities. Investment activities increased in the last quarter of 2020, with stronger signs of recovery in the manufacturing and construction sectors continuing into the quarter ending March 2021.[66] GDP growth is expected to hit 4.8% and 5.4% in 2021 and 2022 respectively.[67]

[65] FSD Uganda, Assessing economic resilience of Ugandan households before COVID 2020
[66] World Bank, Uganda Economic Overview 2021
[67] World Bank, From Crisis to Green Resilient Growth: Investing in Sustainable Land Management and Climate Smart Agriculture (2021)

3.2 Overview on the health sector - Uganda

3.2.1 Healthcare system - Uganda

In Uganda, health services are provided by both the public and private sector. The private health sector comprises of not-for-profit institutions (largely faith-based organizations) and for-profit health providers. Traditional medicine such as Chinese and Ayurvedic medicine is also practiced in Uganda. It is estimated about 60% of Ugandans sought healthcare from such practitioners but only for minor illnesses.[68]

Health services in Uganda are delivered within the framework of decentralization policy. In 1995, the Government of Uganda decentralized delivery of services to improve administrative oversight and service delivery. Local governments have the power to appoint and deploy public servants including health workers within the districts through the District Service Commission. Local governments also plan and oversee service delivery within the districts.[69]

Health infrastructure

Uganda has a total of 6,934 Health facilities of which 45% (3,133) are Government owned. 15% (1,006) are Private and Not-For-Profit (PNFP) while the remaining 40% (2,795) are Private For-Profit (PFP)[70]. Government and Private Not-For-Profit hospitals are mostly higher-level health facilities while Private for-profit facilities majorly consist of lower-level health centres and clinics.

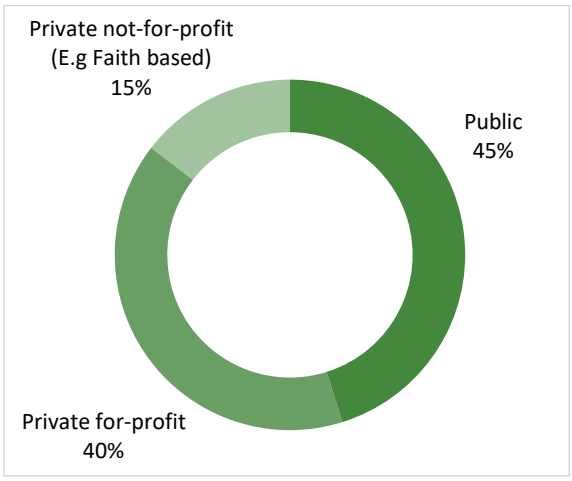


Figure 18: Ownership of health facilities in Uganda (2019, % of total)[71]

The health sector in Uganda is organized in a hierarchy of services effectively starting from health centres at the bottom to national referral hospitals at the apex. Regional Referral Hospitals and National Referral Hospital are semi-autonomous institutions, but only financially. Management of human resources, health information systems, medical equipment and supplies and logistics are still centralized. District health services and general hospitals are managed by local governments.

In 2019, the national health facility density stood at 0.16 per 1,000 population, which is below WHO's recommended target of 0.2 per 1,000.

[68] Ministry of Health, Health Sector Strategic and Investment Plan 2010/11 - 2014/15
[69] Uganda constitution, The Local Government Act. 1997. ACTS SUPPLEMENT No. 1, 24th March 1997.
[70] Ministry of Health, Uganda Master Health Facility List 2019
[71] Ministry of Health, Uganda Master Health Facility List 2019

Level of health facility	Number of facilities
Special clinics	23
National referral hospital	2
Regional referral hospital	13
General hospital	163
Health centre IV	222
Health centre III	1,569
Health centre II	3,364
Clinic	1,578
Total	**6,934**
Ratio per 1,000 population	**0.16**

Table 4: Health facilities by level in Uganda (2019)[72]

Health Workforce

Uganda, just like majority of low-income countries suffers from a shortage of well-trained health workers. This shortage has resulted in Uganda adopting a task shifting strategy. Nurses undertake a range of tasks that were formerly the responsibility of doctors. The density of doctors, midwives and nurses in Uganda stood at 0.56 for every 1,000 inhabitants in 2019.[73] This is below WHOs recommended number of 4.45 professional health workers for every 1,000 inhabitants.

Type of health worker	Number of health workers	Ratio per 1,000 population
Doctors	964	0.02
Midwives	5,868	0.13
Nurses	18,014	0.41
Total	**24,846**	**0.56**

Table 5: Health workforce in Uganda (2019)[74]

3.2.2 Healthcare expenditure - Uganda

Healthcare expenditure in Uganda comes from three main sources – public, private, and external sources. External expenditure account for the largest share of healthcare spending, indicating a high level of donor dependency. There is also a high level of private spending due to the large uninsured population paying out-of-pocket for healthcare services. Public expenditure accounts for the smallest share of healthcare expenditure.

[72] Ministry of Health, Uganda Master Health Facility List 2019
[73] Ministry of Health, Uganda Master Health Facility List 2019
[74] Ministry of Health, Uganda Master Health Facility List 2019

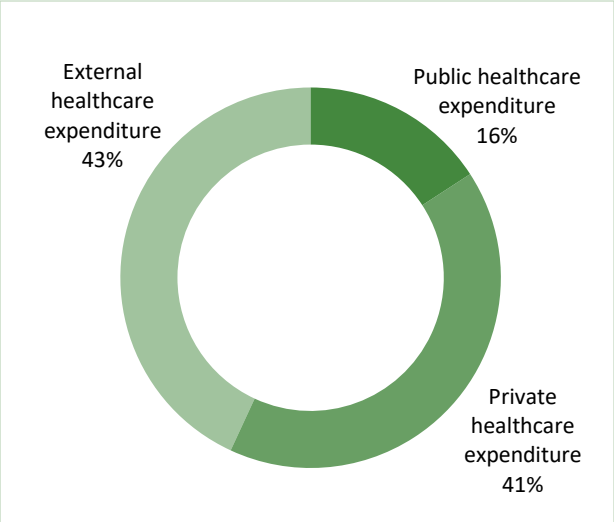


Figure 19: Uganda health expenditure by source (2018, % of total)[75]

Health expenditure per capita has seen a decline from USD 56 in 2011 to USD 43 in 2018. The decrease in per capita expenditure is as a result of health expenditure not keeping up with population growth. Health expenditure has also not kept up with GDP, which has seen the ratio of health expenditure to GDP decline from 8.9% in 2011 to 6.5% in 2018.

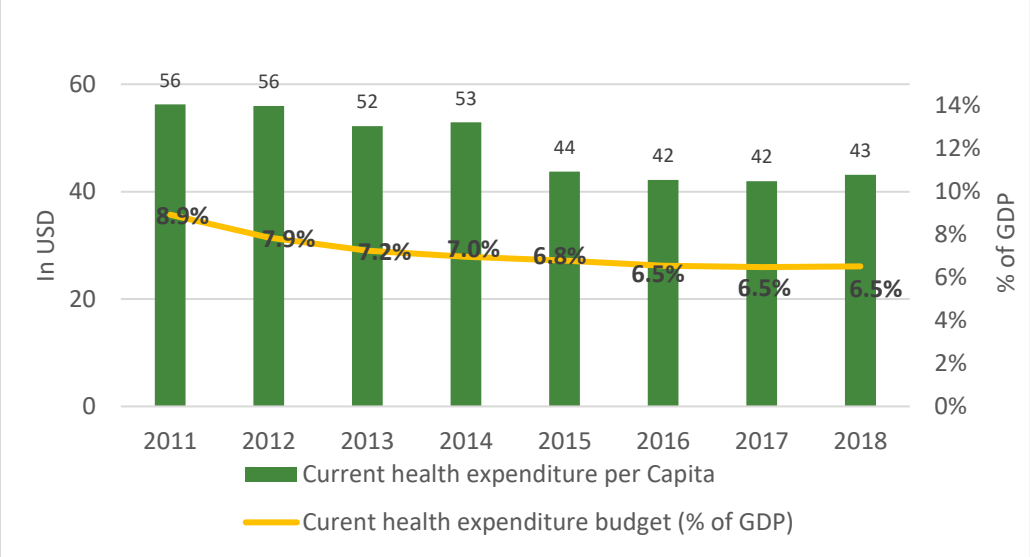


Figure 20: Uganda current healthcare expenditure (2011-2018, Per capita and as % of GDP)[76]

Government budgetary allocation to the health sector has however seen a steady increase from USD 358 million in FY 2015/16 to USD 728.5 million in FY 2019/20.[77] Budgetary allocation as a share of total national budget has also increased from 6.9% in 2015/16 to 7.2% in FY 2019/20.

[75] World bank, 2018
[76] World bank, 2018
[77] Ministry of health, Annual Health Sector Performance Report 2019-2020

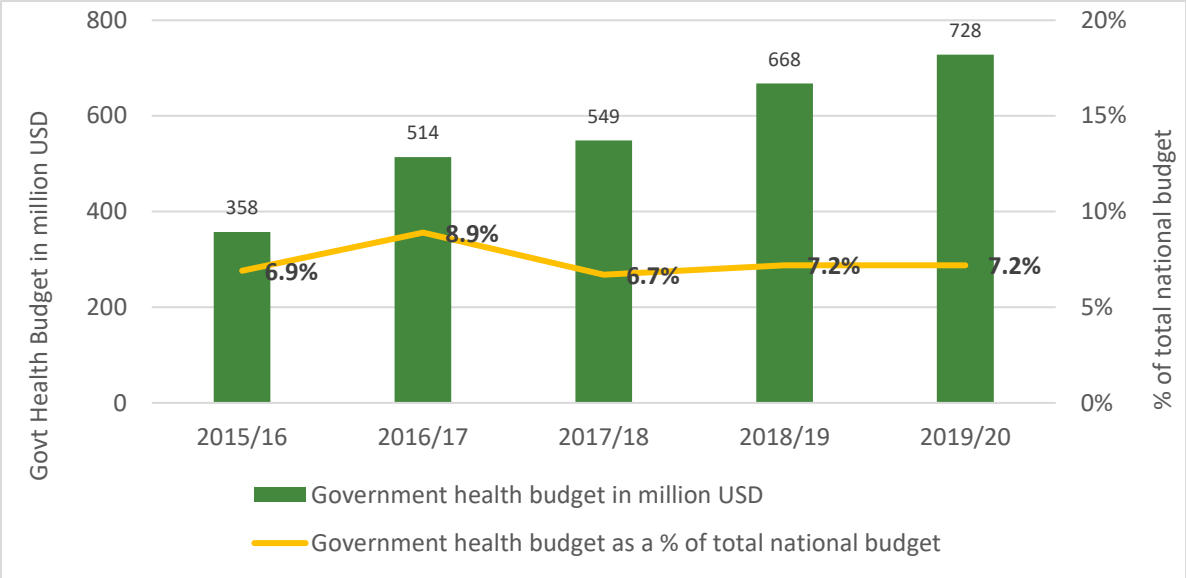


Figure 21: Uganda national health budget and its share of total national budget (2015 – 2020, million USD and % growth)[78]

3.2.3 Disease burden and trends - Uganda

Uganda faces the double burden of having to simultaneously addresses infectious diseases and non-communicable diseases (NCDs). This rise in the burden of NCDs is associated with demographic and social changes, urbanization, aging population, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption.

Top 10 diseases causing death 2009		Top 10 diseases causing death 2019		% change in deaths 2009-2019
1	HIV/AIDS	1	Neonatal disorders	-9.5%
2	Malaria	2	Malaria	-44.4%
3	Neonatal disorders	3	HIV/AIDS	-69.0%
4	Lower respiratory infections	4	Lower respiratory infections	-7.4%
5	Tuberculosis	5	Tuberculosis	-7.0%
6	Diarrheal diseases	6	Stroke	-26.7%
7	Stroke	7	Diarrheal diseases	-10.5%
8	Congenital defects	8	Ishemic heart diseases	32.5%
9	Ishemic heart diseases	9	Congenital defects	-4.5%
10	Meningitis	10	STIs	93.1%
16	STIs	15	Meningitis	-32.6%

Table 6: Top 10 diseases causing deaths in Uganda (2009, 2019, % change)[79]

[78] Ministry of health, Annual Health Sector Performance report, 2019/2020 -Pg.51
[79] IHME, 2019

Between 2009 and 2019, only ischemic heart diseases and sexually transmitted diseases (STD)-related deaths saw a positive increase among the top 10 diseases causing death.

Although significant progress has been made towards containing the threat of communicable diseases such as HIV/AIDS, Malaria, tuberculosis and lower respiratory infections, their burden to the health sector is still significant. Despite Malaria and HIV/AIDS related deaths declining by 44.4% and 69% respectively between 2009 and 2019, they remained the second and third largest killer. The large decline has been as a result of significant resources especially from donors being deployed to fight these diseases.

Neonatal disorders became the leading cause of death in 2019 despite a decline in related deaths by 9.5%. The common causes of neonatal deaths in Uganda are birth asphyxia, prematurity, and sepsis.[80] Majority of mothers in rural and poor households are not attended by a skilled health personnel during birth. The result is not just maternal deaths, but also low levels of education about caring for new-borns. There are issues around the importance of breast feeding and ensuring that babies receive the necessary vaccines required to be given directly after birth and during follow up visits for the remainder of early childhood.
This rise NCD is expected to result in an increasing demand for new medical equipment and technology for diagnosing and managing emerging chronic diseases such as cardiovascular diseases.

[80] UNICEF, Uganda Maternal and New-born Health Disparities - 2015

3.3. Medical and laboratory equipment landscape - Uganda

3.3.1. Medical and laboratory equipment value chain - Uganda

Almost all medical devices used in Uganda are imported with domestic production primarily focused on basic consumable items. The value chain differs from public to private facilities.

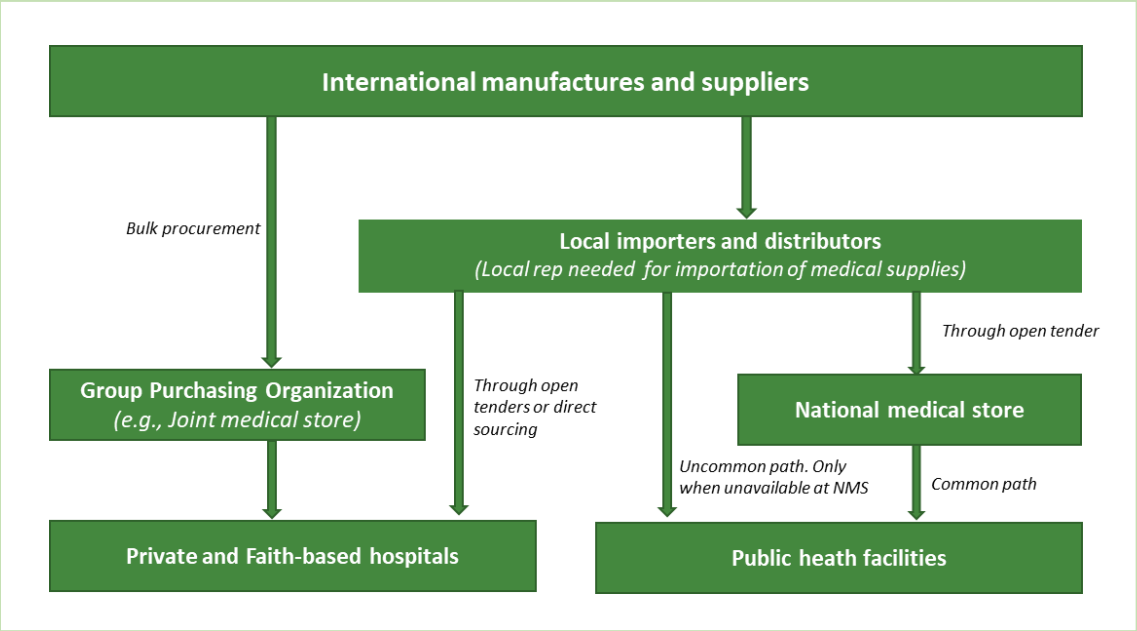


Figure 22: Uganda medical and laboratory equipment value chain (2021)[81]

Public Sector

In the public sector, procurement of medical supplies is centralized through the National Medical Store (NMS), the lead government supply chain agent. NMS is mandated with procuring, warehousing, and distributing medical commodities to all public health facilities in the country. It has a priority over other private distributors when it comes to selling to public health facilities.

Capital intensive equipment procurement on the other hand does not always follow the NMS route. Since capital intensive medical and laboratory equipment is rarely procured in bulk, procurement can be done directly from private distributors either by the hospitals (for national and referral hospitals) or the local government responsible for the health facility.

Private sector

In the private sector, procurement of medical supplies is done directly from distributors. Health facilities procure essential medical supplies and other consumables either through independent distributors or group purchasing organizations. The main group purchasing organization in Uganda is the Joint Medical Store (JMS), a private-not-for profit (PNFP) non-governmental organization (NGO) established as a joint venture between the Uganda Catholic Medical Bureau (UCMB) and the Uganda Protestant Medical Bureau (UPMB). Its mission is to supply medicines, medical and laboratory equipment, and related healthcare services of assured quality to over 3000 healthcare facilities. Capital intensive medical and laboratory equipment is procured directly from distributors.

[81] africon research, 2021

3.3.2. Import trends of medical and laboratory equipment - Uganda

Import of medical equipment saw strong growth between 2011 and 2020, with the import value doubling from USD 25 million to USD 50 million. Imports were not negatively affected by COVID-19 with 2020 being Uganda's highest importing year. The 8% CAGR between 2011 and 2020 is expected to continue for the next 5 years.

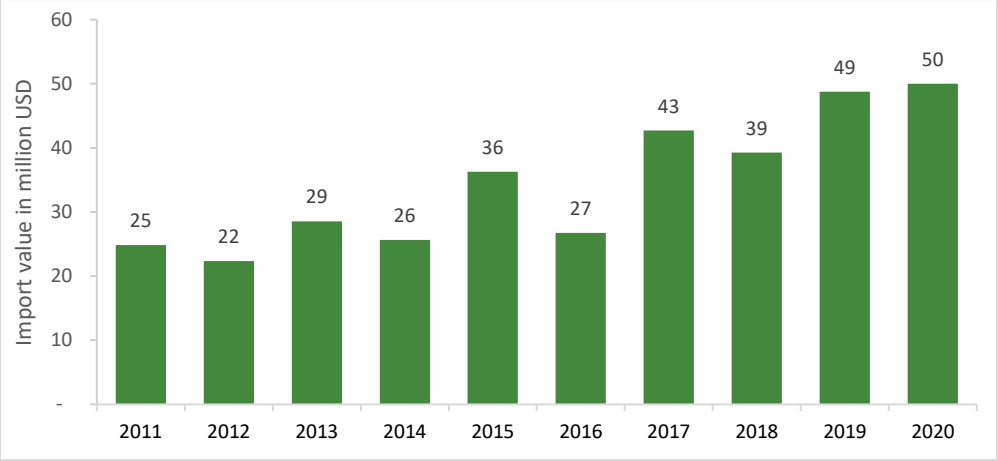


Figure 23: Uganda import value of medical equipment (2011 – 2020, million USD)[82]

Laboratory equipment imports on the other hand only grew by 38% between 2011 to 2020, increasing from USD 13 million to USD 18 million. Growth is expected to maintain its current trend of 3.7% CAGR for the next five years.

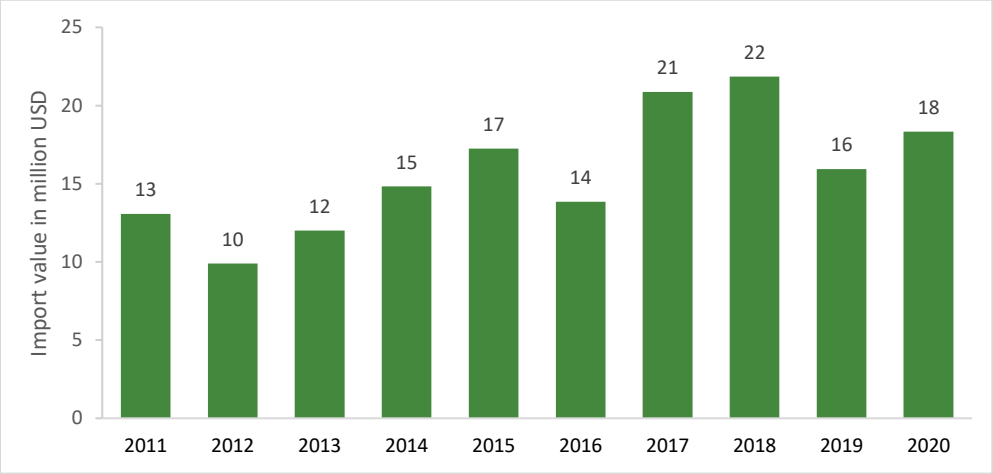


Figure 24: Uganda import value of laboratory equipment (2011 – 2020, million USD)[83]

COVID-19 lead to high demand for therapeutic respiratory apparatuses in 2020. Respiratory problems were the main complication faced by COVID-19 patients. However, with COVID-19 cases declining significantly in 2021, imports are expected to drop below pre-pandemic levels as most hospitals will be left with excess capacity built up during the height of the pandemic.

[82] UN Comtrade, 2021
[83] UN Comtrade, 2021

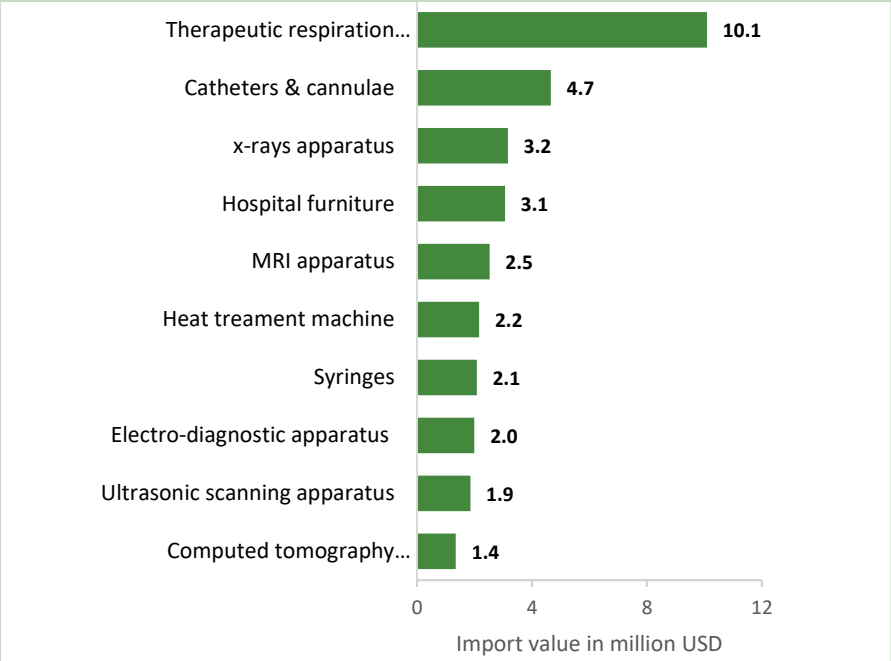


Figure 25: Uganda top 10 medical equipment Imports (2020, million USD)[84]

Optical radiation apparatuses, heat treatment machines and microtomes were the top three laboratory equipment imports in 2020. This has been consistent with past years indicating that demand was stable despite COVID-19. Rectifying plants, centrifuges, and optical radiation apparatuses were the strongest growing product segments between 2012 and 2020 increasing by 595%, 291% and 239% respectively. They are expected to maintain this strong growth for the next five years.

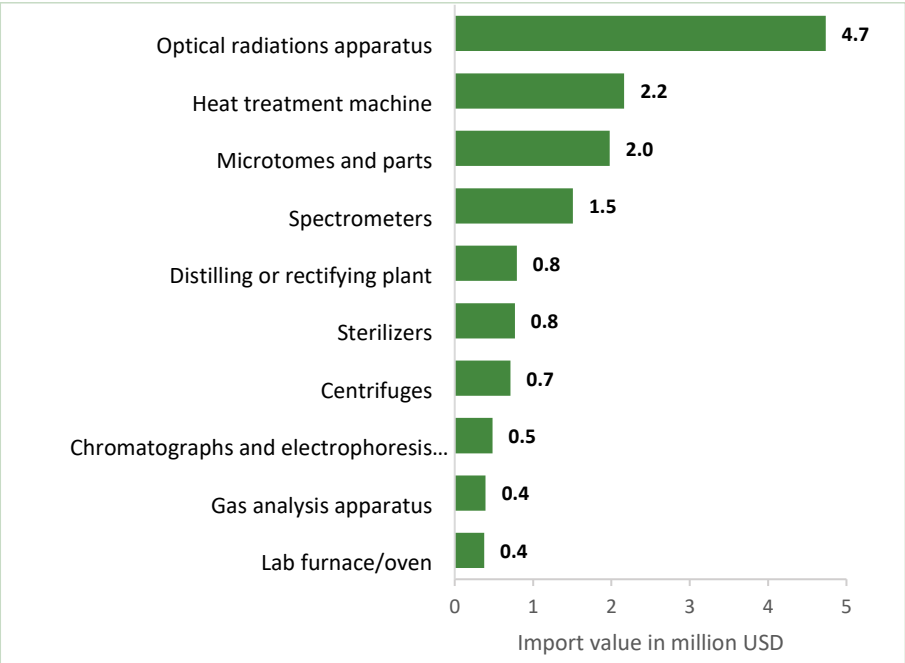
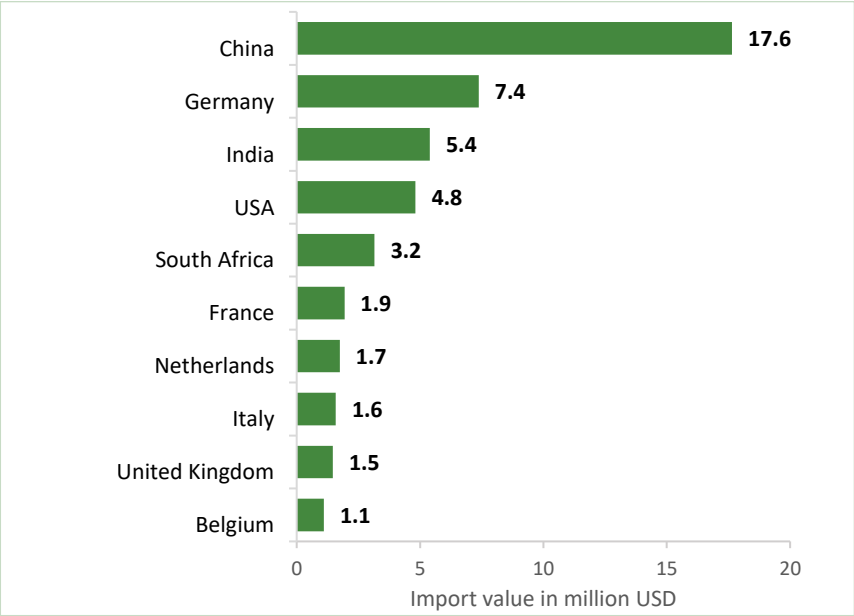


Figure 26: Uganda top 10 laboratory equipment Imports (2020, million USD)[85]

[84] UN Comtrade, 2021
[85] UN Comtrade, 2021

China is by far the leading source of imports for medical equipment with about 35% market share. However, Western countries account for a combined market share of about 44% of medical equipment imports in Uganda.



Western countries dominate the laboratory equipment segment with a market share of 60%. Germany is the market leader with a market share of 17%. India and China, both considered low-cost sources of laboratory equipment have a market share of 17% and 10% respectively. Netherlands and South Africa have seen the biggest increase in laboratory exports to Uganda between 2012 and 2020, growing 858% and 572% respectively.

Figure 27: Origin of medical equipment imports in Uganda (2020, million USD)[86]

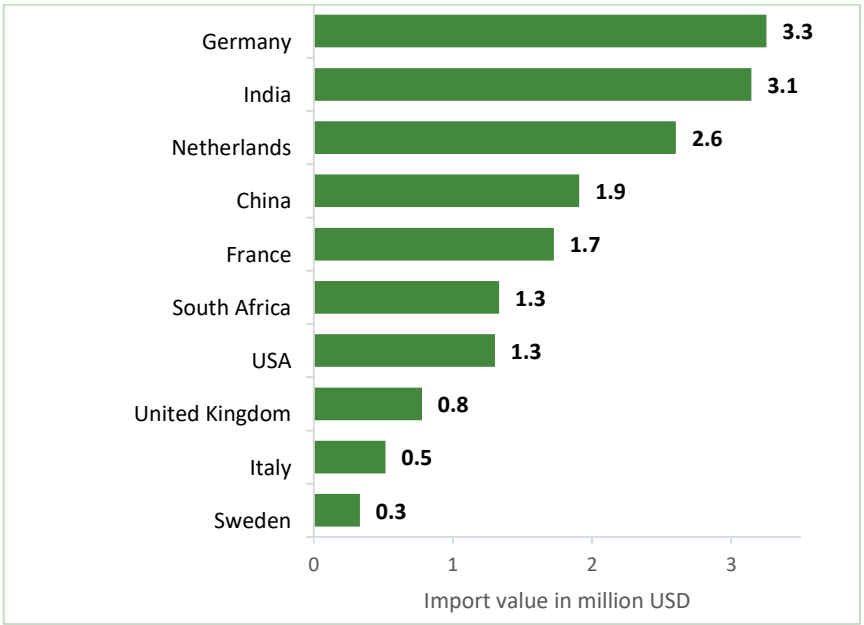


Figure 28: Origin of laboratory equipment imports in Uganda (2020, million USD)[87]

[86] UN Comtrade, 2021
[87] UN Comtrade, 2021

3.3.3. Medical and laboratory equipment investment decision-making process - Uganda

Capital investment decisions on medical technology is usually a participative process. Various stakeholders including product users, hospital administrators, accounting officers, procurement officers, and hospital management have their input into the final decisions. The process typically starts with the user, in most cases lab managers or physicians putting forward a request for new equipment. The user is tasked with providing clinical and business relevant information to justify investment. The stakeholders will evaluate the purchase based on key metrics that may include return on investment, immediate needs, hospitals technical capacity as well as the competitive edge the equipment would provide against competitors' products.

Procurement in the public sector is challenging due to bureaucratic delays and limited budgets. The government has huge budgetary constraints with significant proportions of their annual allocations going to recurrent expenditures, particularly wages. This means too few resources are left for investment in medical and laboratory equipment.

In the private sector, the process is usually top-down, depending on the financial feasibility. The Heads of Departments put out a need for equipment alongside the implications for investment. The hospital committee evaluates the request based on current needs before forwarding it to the board for approval. Whereas public hospitals would gazette a call for tenders, private hospitals typically work with known equipment dealers or place orders with the equipment manufacturers directly to save on investment costs by cutting out the middleman.

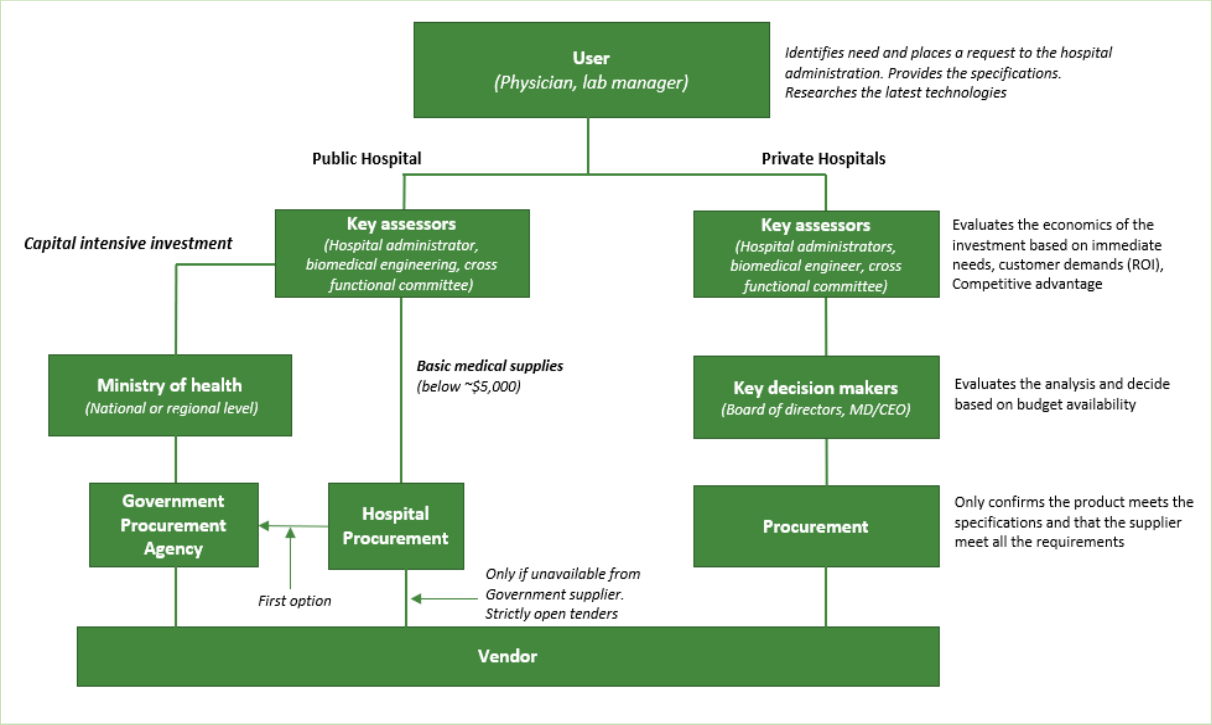


Figure 29: Medical and laboratory equipment investment decision-making process in Uganda (2021)[88]

Source of information on new medical technology

[88] africon research 2021

According to research conducted by africon across the health sector in Uganda, all healthcare facilities confirmed to have learnt about new medical technology via direct contact with vendors. Another popular way hospitals learn about new technologies is through colleague recommendation and the use of online resources. Conferences and trade shows were found to be the least popular way to learn about new technology due to cost of attendance.

Purchasing criteria

Based on the research conducted by africon, hospitals and labs surveyed mentioned that pricing and quality were the most important purchasing criteria considered. For pricing, it is thus not surprising that China featured prominently in the top supplier countries of medical and laboratory equipment. Other criteria considered were brand familiarity and references from industry experts. Also, about 80% of the medical and laboratory equipment procured were publicly tendered, whiles few transactions were achieved by single sourcing.

3.3.4. Medical and laboratory equipment regulation - Uganda

The National Drug Authority (NDA) regulates the import, manufacture, export, and supply of medical devices in Uganda to safeguard public health. Medical devices are regulated under a ministerial decree ADM.140/323/01 of 20th July 2020 and statutory Instrument no 77 of the Surgical Instruments and Appliances Regulation 2019.

According to the National Drug Authority (NDA), a medical device refers to any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
    i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
    ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
    iii. investigation, replacement, modification, or support of the anatomy or of a physiological process;
    iv. supporting or sustaining life;
    v. control of conception;
    vi. disinfection of medical devices;
    vii. providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

Import process

All medical devices to be imported into Uganda must be registered by the National Drug Authority (NDA). Application for registration of medical devices should be submitted by either the manufacturer or an authorized local agent of the manufacturer, also known as Local Technical Representative (LTR), who should be either company licensed to deal in medicines and/or medical devices, or a diagnostic laboratory, hospital, health centre or clinic.

The application should include a cover letter, product details, manufacturer details, certificate of analysis confirming compliance to a quality system standard (e.g., ISO), evidence of repeat sales in country of manufacture as well as product samples. Once registration is approved, it is valid for five years subject to consistent quality and satisfactory performance of the device in the market.

Once registration is done, the importer can apply for an import permit. A registered importer applies for an import permit by filling an application form which should be accompanied by a proforma invoice. Once submitted to NDA, a verification certificate corresponding to the medical devices to be imported is issued by NDA. This is a go ahead that the items specified on the verified proforma invoice can now be shipped or airlifted. The certificate is valid for 12 months.

Before shipping to Uganda, medical devices are subject to Pre-export Verification of Conformity (PVoC) and therefore must obtain the mandatory custom clearance documents and certificate of conformity (CoC). PVoC is carried out by authorized third-party agencies appointed by the Uganda National Bureau of Standards (UNBS) who include TUV Rheinland, Intertek and SGS.

On arrival at the ports of entry, NDA may inspect the consignment to ensure that they comply with the approved specifications and regulations before they are released. Each consignment must be accompanied by an import permit, an original proforma invoice and a corresponding certificate of analysis.

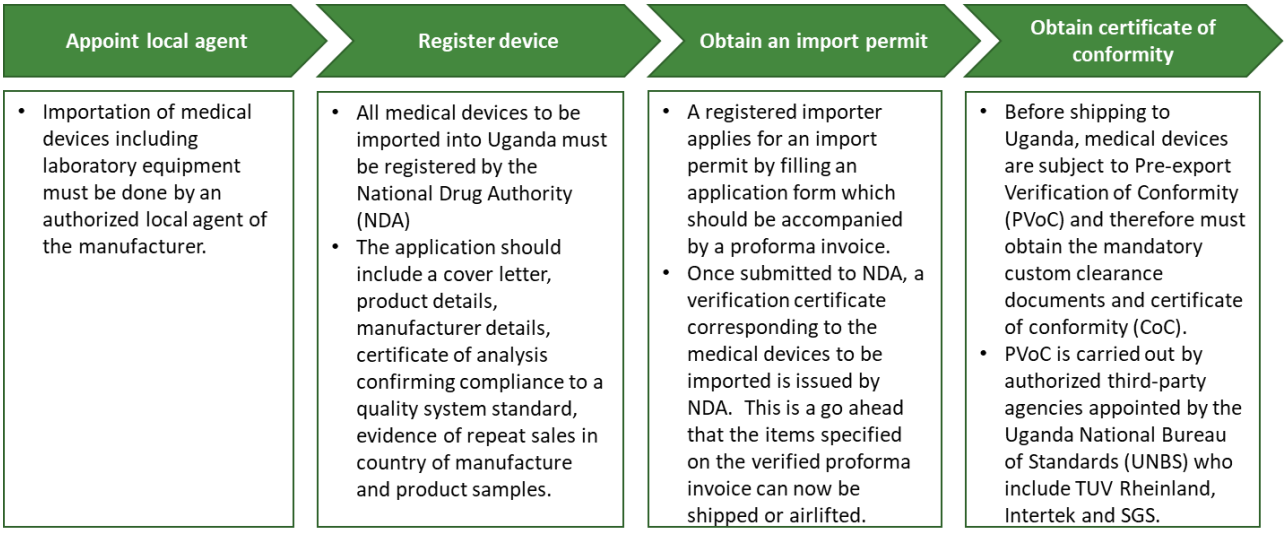


Figure 30: Uganda medical and laboratory equipment import process (2021)[89]

[89] africon research 2021

3.3.5. E-health in Uganda

The state of E-health in Uganda

The Government of Uganda recognises e-health as an enabling platform to improve healthcare delivery. It allows doctors to consult and diagnose remotely, access patients' medical information, provide district health information surveillance data and in addition facilitate research studies.

According to research conducted by africon on the healthcare sector in Uganda, it was found that the majority of private hospitals have already adopted an e-health system but mainly for patients record keeping. Other benefits such as telemedicine and online procurement are yet to be leveraged fully. Large public hospitals, especially national and referral hospitals, have also adopted e-health systems. This is however not the case for lower-level hospitals, and it was non-existent in rural hospitals. The majority of health facilities with e-health systems had acquired them recently with the average age of an e-health system being around three years old.

E-health adoption challenges

Adoption of e-health does not come without its limitations with the largest barrier being cost. Other limitations include low digital literacy, inadequate technical expertise, unreliable power supply and poor internet coverage especially in rural areas. The Ugandan health sector is characterised by a fragmented landscape of e-health pilot projects. Numerous data and health information system (HIS) silos are significant barriers to the effective sharing of information between healthcare participants, making the integration and scalability of these systems a challenge.

E-health policies

The government, partners, and private institutions are continuing to invest in various e-health initiatives. However, without some form of a national plan and coordination, there is a real risk of continued duplication, ineffective expenditure, and the creation of new solutions that cannot be integrated or scaled across the continuum of care. For this reason, the Ministry of Health developed a National eHealth Policy (2016) to guide the use of ICT in supporting health sector transformation. This was done through a series of national consultations that included health sector professionals, partners, faith-based organizations, government, non-governmental organizations (NGOs), and other stakeholders. The National eHealth Policy and Strategy (2016) provides an appropriate basis to guide the development of e-health in Uganda. It emphasizes on leveraging already existing opportunities as a means of accelerating e-health roll out.

3.3.6. E-learning in Uganda

Health training landscape

Training of health professionals in Uganda is dominated by private institutions. Economic shocks in the 1970s saw government introduce policy actions that slowed down publicly funded training of health workers. According to the Allied Health Professional Council of Uganda (AHPCU), there are 64 accredited health training institutions in Uganda. 52 (81%) of these institutions are privately owned while only 12 (19%) are public.[90] For nursing and midwifery training, out of the 87 recognised

[90] Allied Health Professionals Council 2019

institutions, 11 are government-owned, 27 are faith based and 49 privately owned.[91] This privatisation of health training has been one of the major causes of the health workers shortage.

Health training is not limited to the classroom, but the majority of programmes require practical training as part of their curriculum. The level of practical curriculum depends on the type of training. Certificate courses have the largest portion of their curriculum held as practical training at 60% of the curriculum, diploma at 50% while advanced programmes including graduate diploma and undergraduate degree having the least amount of practical training of about 30% of the curriculum.

E-learning in health training

E-learning is yet to be widely adopted in health training, but the COVID-19 pandemic accelerated its adoption due to the imposed lockdowns which made in-person training impossible.

However, according to africon's research across health training institutions in Uganda, the roll out of e-learning has not been without its challenges. All 3 institutions had never designed an online course before 2020. Teachers at these institutions favoured the traditional face-to-face lecture method. Teachers lacked the skills for course design and use of the e-learning systems to be able to design proper online courses with appropriate learning outcomes. On the student's side, inadequate tools to access e-learning material, poor internet service and unstable power were the biggest challenges. During the COVID-19 period, practical lessons were deferred until the universities were back to in-person classes.

Uganda did not have any government policy guiding e-learning before the pandemic hit. However, in June 2020, the National Curriculum Development Centre (NCDC), the body mandated to regulate the provision of Higher Education in Uganda, moved in to regulate and standardize e-learning, through introduction of open, distance, and e-learning. (ODEL) framework. This was however an emergency guideline to enable higher education institutions resume teaching.

[91] Uganda Nurses and Midwives Council 2021

4. Tanzania mainland

4.1. Country profile – Tanzania mainland

Geography

Tanzania is an East African country. It borders Uganda and Kenya to the north, Indian Ocean to the east, Mozambique to the south, and Malawi, Zambia, the Democratic Republic of the Congo, Burundi and Rwanda to the west. Land cover is dominated by woodland, grassland and bushland which account for about 80 percent of the total area. Agricultural land is estimated to be about 42 percent of the total area.

Social situation

On the Human Development Index (HDI), Tanzania ranks 163rd out of 189 countries. In education, the total adult literacy rate in 2019 stood at 77.9%. Primary school enrolment stood at 98.9%. However, secondary school enrolment stood at a disappointing 32%, which is below Africa's average of 53.5%.

The life expectancy of Tanzanians is 65.5 years. However, 31.8% of children under 5 years are malnourished and infant mortality rate is high at 50.3 per 1,000 live births.[92] 55% of the population experiences various deprivations such as poor health, lack of education, inadequate living standards, disempowerment, poor quality of work, the threat of violence, and living in areas that are environmentally hazardous.[93]

Macroeconomic overview

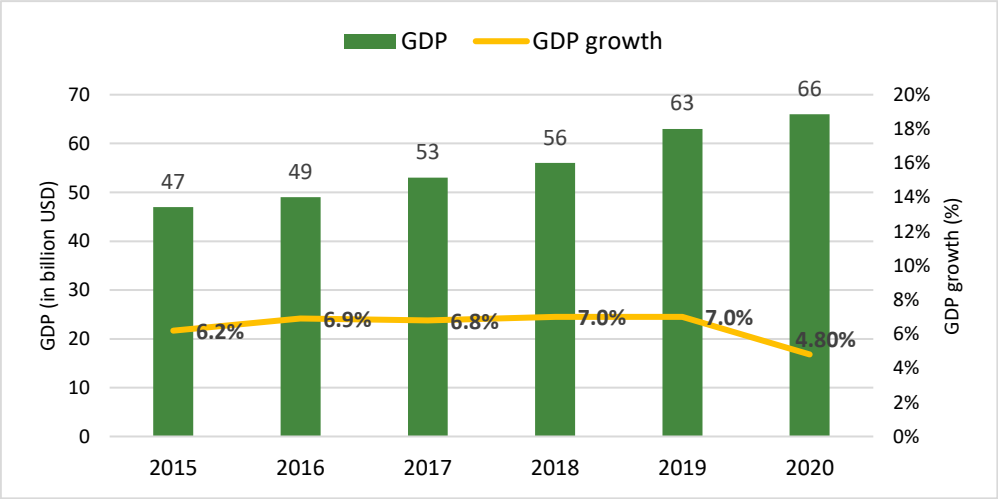


Figure 31: Tanzania GDP and GDP growth rate (2015 – 2020, billion USD and % growth)[94]

Following two decades of sustained growth, Tanzania reached an important milestone in July 2020, when it formally graduated from low-income country to lower-middle-income country status. Tanzania's achievement reflects sustained macroeconomic stability that has supported growth, in addition to the country's rich natural endowments and strategic geographic position. Pre-COVID-19, Tanzania was one of the fastest growing economies on the continent. The annual GDP growth rate

[92] UNICEF
[93] Oxford Poverty & Human Development Initiative (2021), Multidimensional Poverty
[94] Ministry of Finance (Tanzania mainland), Economic survey 2020

averaged 6.3% between 2010 and 2019. In 2020, Tanzania fared relatively well compared to its regional peers despite the economic slowdown. The real gross domestic product (GDP) growth rate fell from 6.8% in 2019 to an estimated 2.09% in 2020.

GDP Composition

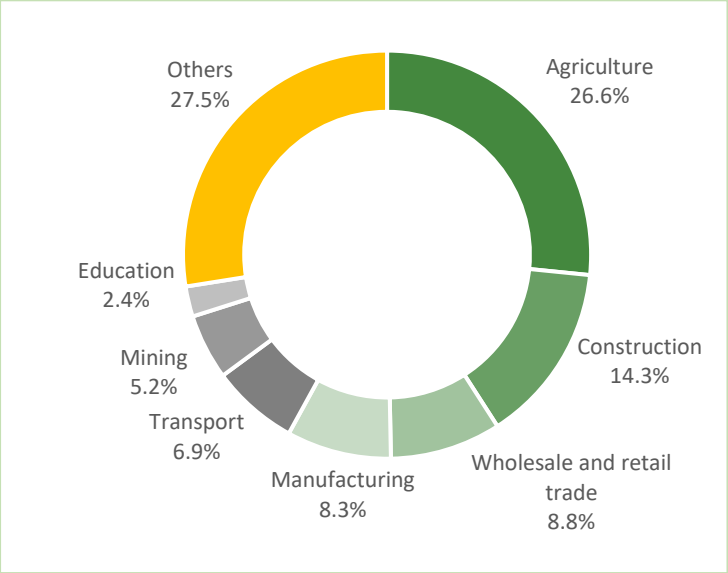


Figure 32: Tanzania GDP composition (2020, % of total)[95]

Tanzania is an agrarian economy as such agriculture is a fundamental sector to the country. The sector employs 68% of the total workforce.[96] Tanzania has the third largest livestock population in Africa comprising 25 million cattle, 98 percent of which are indigenous breeds, complemented by 16.7 million goats, 8 million sheep, 2.4 million pigs, and 36 million chickens.[97]

The construction industry has been one the biggest contributors of growth to the Tanzanian economy. This has been primarily driven by the heavy government investment in public infrastructure projects such as the standard gauge railway.[98]

The manufacturing sector in Tanzania is mainly agro-based. It plays an important role in adding value to agricultural output with key industries including dairy processing, grain milling, beverages manufacturing and tobacco products industries.

COVID-19 impact

Although the government did not impose stringent restrictions, the COVID-19 pandemic prompted firms and consumers to adopt precautionary behaviours, hindering domestic economic activity. The tourism sector came to a sudden halt while exports of manufacturing and agricultural goods slumped. Data from the Bank of Tanzania revealed that in the year ending December 2020, Tanzania's travel receipts declined by 59.2%.[99] Tanzania also experienced scarcity of imported raw materials for industrial production as a result of international logistical disruption. During this same

[95] Bank of Tanzania, Annual publication 2020
[96] FAO 2020
[97] FAO 2020
[98] Tanzania invest (2019), Construction Sector Overview
[99] Tanzania Invest (2020), Covid-19 in Tanzania

period, an estimated 140,000 formal jobs were lost, and another 2.2 million nonfarm informal workers suffered income losses.[100]

Outlook

The economy is forecasted to grow at annual growth rate of 5.5% and 6.0% in 2021 and 2022 respectively. This is due to the reopening of trade corridors and resumption of tourist activities. The major downside risks include business regulatory bottlenecks that constrain private sector activity and uncertainties regarding the pandemic. Poverty and unemployment are expected to remain high due to depressed private sector activity.[101]

[100] World Bank 2021
[101] AfDB, Tanzania Economic Outlook 2021

4.2 Overview on the health sector – Tanzania mainland

4.2.1 Healthcare system – Tanzania mainland

Tanzania's healthcare system is made up of both public and private stakeholders. The primary public stakeholder is the Ministry of Health and Social Welfare (MOHSW) and other supporting ministries such as the Ministry of Finance and Economic Affairs (MOFEA) and Ministry of Science, Technology and Higher Education (MSTH). At the national level, MOHSW is responsible for formulating polices and overseeing all health functions in the country. MOFEA is responsible for disbursing health funds while MSTH is responsible for the training of health professionals.

Following the 1998 local government reforms which emphasised devolution and decentralisation at the local levels, the local government authorities now have greater autonomy on finance and policy implementation. With oversight from the Prime Minister's Office, the regional and local government authorities are responsible for planning, financing, and overseeing delivering health services at the local level.

Health infrastructure

There are a total of 9,813 health facilities registered in Tanzania. 63% of these facilities are publicly owned while 37% are private.[102] Private health facilities include both for-profit and not-for-profit facilities mainly operated by Faith-based organizations.

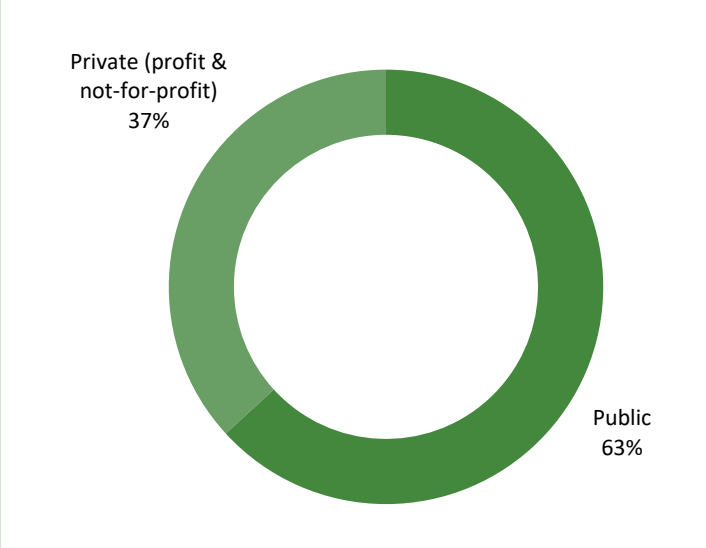


Figure 33: Ownership of health facilities in Tanzania (2021, % of total) [103]

Tanzania's health system follows a decentralised and hierarchical structure, which is in tandem with the political-administrative hierarchy. At the base are the dispensaries and health centres. These are at the frontline in providing primary curative and preventative health services. They are the main source of health services for the majority of the population, particularly in rural areas. Above health centres and dispensaries are district hospitals, which are found in every district. A district that does not have a public district hospital enters into a service agreement (contractual agreement) with a

[102] Tanzania health facility registry, 2021
[103] Tanzania health facility registry, 2021

hospital run by a faith-based organization, which is then designated as a district hospital.[104] Above district hospitals are regional referral hospitals, zonal hospitals, and finally the National Hospital.

The national health facility density in 2021 stands at 0.16 per 1,000 population, which is below WHOs recommended target of 0.2 per 1,000.

Level of health facility	Number of facilities
Referral/Specialized Hospital	4
Zonal Hospital	8
Regional Referral Hospital	25
District Hospital	343
Health Centre	928
Dispensary	6,967
Nursing and maternity homes, clinics etc.	908
Total	**9,183**
Ratio per 1,000 population	**0.16**

Table 7: Health facilities by level in Tanzania (2021)[105]

Health workforce

Tanzania suffers from a shortage of health workers despite the high number of health professionals it trains every year, many cannot be absorbed into the public health system due to governmental financial hardship. For instance, between 2015-2018, more than 10,000 middle level cadres were trained but only about 1,500 were absorbed.[106] It is estimated that up to 30% of all healthcare workers trained in the country left the country within a year after completing their training.[107] Health workers shortage is a lot more extreme in rural areas due to lack of attractive retention schemes, poor remuneration, as well as insufficient equipment and medicine to do the work. Physicians prefer practicing in urban settings where they can `moonlight´, in their private practices or work multiple shifts at different hospitals and clinics, to supplement low salaries.

Type of health worker	Number in health workers	Ratio per 1,000 population
Medical Doctor (MD)	2,190	0.04
Nurse/Nurse Midwife	30,451	0.52
Total	**32,641**	**0.56**

Table 8: Health workforce in Tanzania (2020)[108]

In 2020, the national health workforce density of doctors, nurses and midwives stood at 0.56 per 1,000 population which is way below the minimum threshold of 4.45 per 1,000 population recommended by WHO.[109]

[104] WHO 2017, PRIMASYS: comprehensive case study from United Republic of Tanzania
[105] Tanzania health facility registry, 2021
[106] Ministry of health, Mid Term Review of the Health Sector Strategic Plan IV 2015 - 2020
[107] Global health delivery, Addressing Tanzania's Health Workforce Crisis Through PPP 2016
[108] AllAfrica, 2020
[109] WHO 2016, Health workforce requirements for UHC and the SDGs

4.2.2 Healthcare expenditure – Tanzania mainland

Healthcare spending in Tanzania comes from three main sources – public, private, and external sources. Even though public expenditure plays the largest role in the financing of health service, Tanzania is heavily reliant on donor financing to meet its health needs. 31% of total expenditure comes from external sources. Private spending accounts for the smallest share of healthcare expenditure due to a relatively functional public insurance scheme.

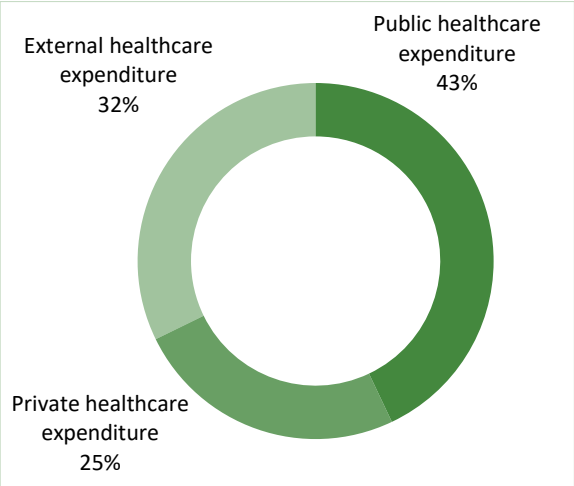


Figure 34: Tanzania health expenditure by source (2018, % of total)[110]

Health expenditure per capita has seen a marginal decline over the years, dropping from USD 38 per capita in 2011 to USD 37 per capita in 2018. The decrease in per capita expenditure is caused by health expenditure not keeping up with the growing population. Health expenditure has also not kept up with GDP. The health expenditure ratio to GDP in 2018 was 3.6%, which was a decline from 2011 when this figure stood at 5.1%.

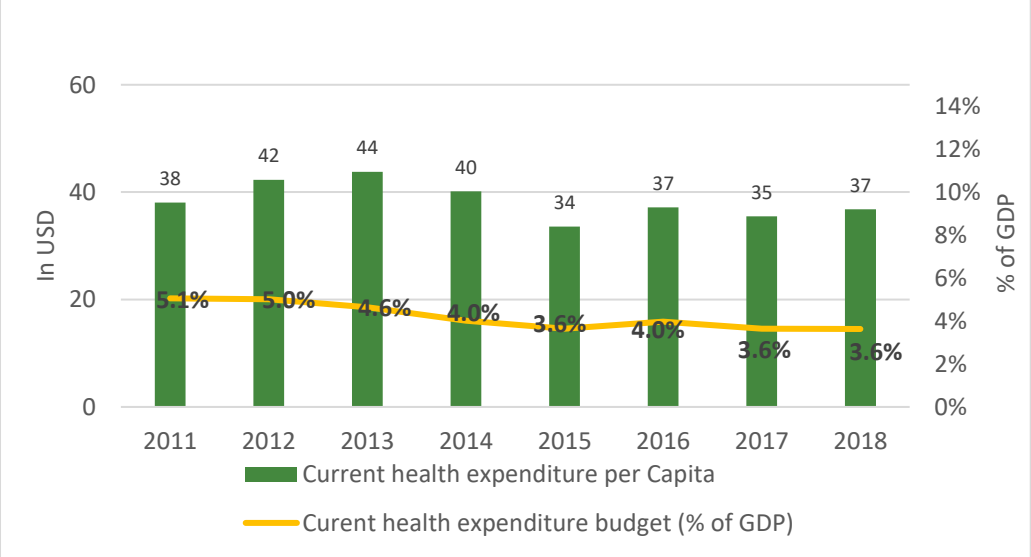


Figure 35: Tanzania current healthcare expenditure (2011-2018, Per capita and as % of GDP)[111]

[110] World bank 2021
[111] World bank 2021

The health sector budget only increased by 5.6% from USD 904 million in FY 2015/16 to USD 955 million in FY 2020/21.[112] Budgetary allocation as a share of total national budget declined from 7.1% in FY 2016/17 to 5.7% in FY 2020/21. It is common for the actual amount that gets disbursed to the health ministry to be significantly lower than the promised amount in the national budget due to the government either failing to meet its revenue targets or donors failing to commit to their promise.

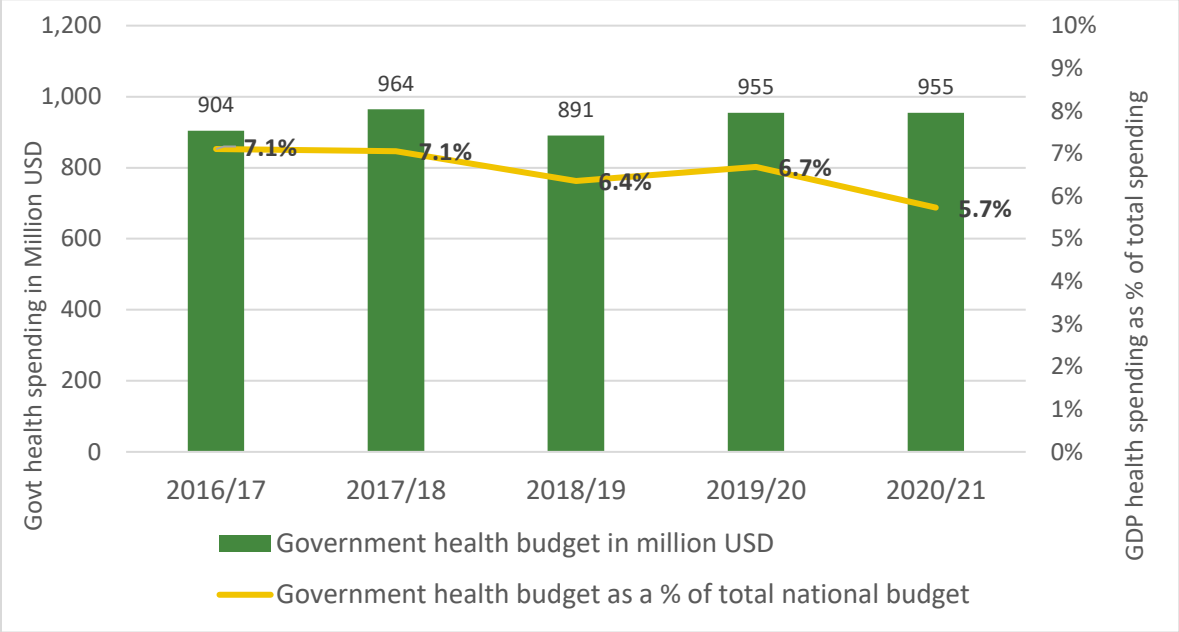


Figure 36: Tanzania national health budget and its share of total national budget (2016 – 2021, million USD and % growth)[113]

4.2.3 Disease burden and trends – Tanzania (including Zanzibar)

Tanzania faces a double burden to its health system by having to not only deal with infectious diseases that have historically plagued the country, but also address the rise of non-communicable diseases (NCDs). This rise in the burden of NCDs is associated with demographic and social changes, for example urbanization, aging population, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption.

Stroke, ischemic heart diseases and cirrhosis were the only top 10 diseases to see a positive increase in deaths between 2009 and 2019. All these three conditions can be attributed unhealthy lifestyle, and this is expected to continue being a burden to the Tanzania health system as the country continues to urbanize.

HIV, tuberculosis and malaria related deaths have seen a decline, but their burden is still significant despite the heavy resources deployed to fight them especially by donors.

Neonatal deaths have become the leading killer in Tanzania despite a decline of 4.8% between 2009 and 2019. The mortality rates for children under five is estimated at 50 per 1,000 live births[114]. It is estimated that 320 children under 5 years of age die every day due to preventable causes. 39% of

[112] MOHSW, Annual Health Sector Performance Report 2019-2020
[113] UNICEF, Tanzania Health budget brief (2020-2021)
[114] UNICEF, 2021

these deaths occur in the first 28 days of life and 70 per cent occur before the first birthday.[115] Approximately 1 out of 3 women who give birth are not attended to by skilled health personnel[116]. The result is not just maternal deaths, but also low levels of education about caring for new-borns. Issues exist around the importance of breast feeding, ensuring that babies receive the necessary vaccines required to be given directly after birth and during follow up visits for the remainder of early childhood.

This rise of non-communicable diseases (NCDs) expected to result in an increasing demand for new medical equipment and technology for diagnosing and managing emerging chronic diseases such as cardiovascular diseases.

Top 10 diseases causing death 2009		Top 10 diseases causing death 2019		% change in deaths 2009-2019
1	HIV/AIDS	1	Neonatal disorders	-4.8%
2	Neonatal disorders	2	Low respiratory infections	-14.0%
3	Low respiratory infections	3	HIV/AIDS	-68.8%
4	Tuberculosis	4	Stroke	23.7%
5	Diarrheal diseases	5	Tuberculosis	-4.9%
6	Malaria	6	Ischemic heart diseases	37.9%
7	Stroke	7	Malaria	-12.1%
8	Congenital defects	8	Diarrheal diseases	-21.5%
9	Ischemic heart diseases	9	Congenital defects	-8.5%
10	Malnutrition	10	Cirrhosis	4.7
11	Cirrhosis	13	Malnutrition	-28.0%

Table 9: Top 10 diseases causing deaths in Tanzania (2009, 2019, % change)[117]

[115] National Bureau of Statistics, Tanzania Demographic and Health Survey (2015/2016)
[116] UNICEF, Tanzania Health budget brief (2020-2021)
[117] IHME 2019

4.3. Medical and laboratory equipment landscape – Tanzania mainland

4.3.1. Medical and laboratory equipment value chain– Tanzania mainland

The medical and laboratory equipment value chain is centralized with few stakeholders in the healthcare ecosystem.

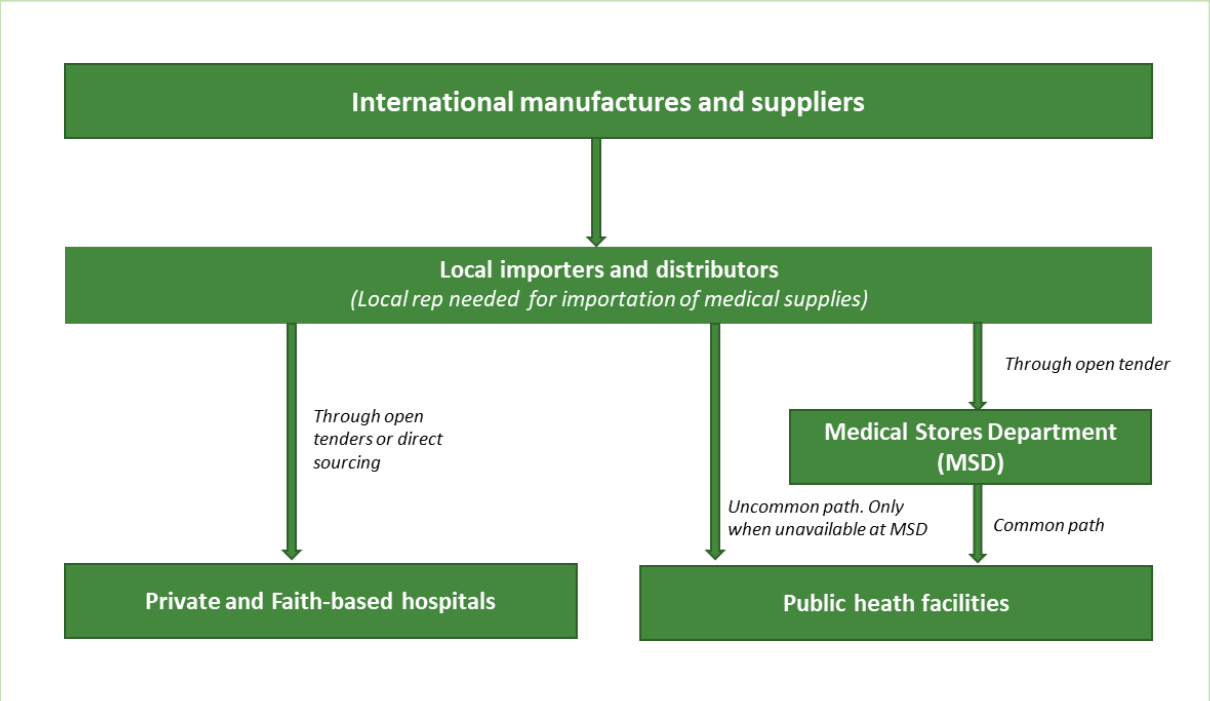


Figure 37: Tanzania medical and laboratory equipment value chain (2021)[118]

Public Sector

In the public sector, the Medical Stores Department (MSD) is the government body with the mandate to develop, maintain and manage an efficient and cost-effective logistics system of procurement, storage and distribution of approved essential medicines and medical supplies for public health facilities.[119] It is the largest importer of medicines and medical supplies in Tanzania. The department leverages on its bulk purchasing capability to source equipment and supplies for public health facilities. Public health facilities are obligated to source their equipment and supplies from the MSD. In rare instances where MSD does not have certain supplies, the National and Zonal hospitals with internal procurement capabilities are allowed to source from independent distributors with clearance from MSD.

MSD is directly funded by the government. The Ministry of Health transfers money to the MSD monthly. The MSD develops a budget which details the amount needed and what products it intends to purchase. In 2021, the annual budget for consumables and medical equipment was USD 140 million.[120]

[118] africon research 2021
[119] Medical Stores Department 2021
[120] africon research 2021

Private Sector

In the private sector, procurement of medical supplies is done directly through independent distributors. Group purchasing organizations are not common in Tanzania.

4.3.2. Import trends of medical and laboratory equipment – Tanzania (including Zanzibar)

Import of medical equipment has seen a steady rise over the past decade growing by 131% between 2011 and 2019 before recording a dip in 2020. COVID-19 resulted in a slowdown in capital investment, which can explain the dip in 2020, but the growth trend is expected to recover in 2021. Tanzania is expected to see a recovery in medical equipment imports in the next five years and is expected to grow at pre-pandemic levels of 11.3% CAGR.

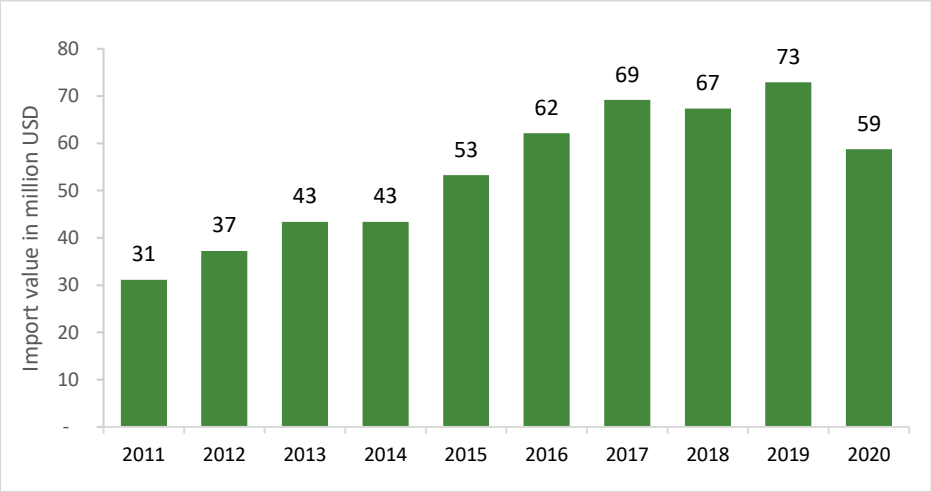


Figure 38: Tanzania import values for medical equipment (2011 – 2020, million USD)[121]

Laboratory equipment imports on the other hand have been relatively flat in comparison to the past decade, only recording a growth of 17% between 2011 and 2020. Laboratory equipment imports are expected to grow at a much slower pace maintaining the current CAGR of 1.8%.

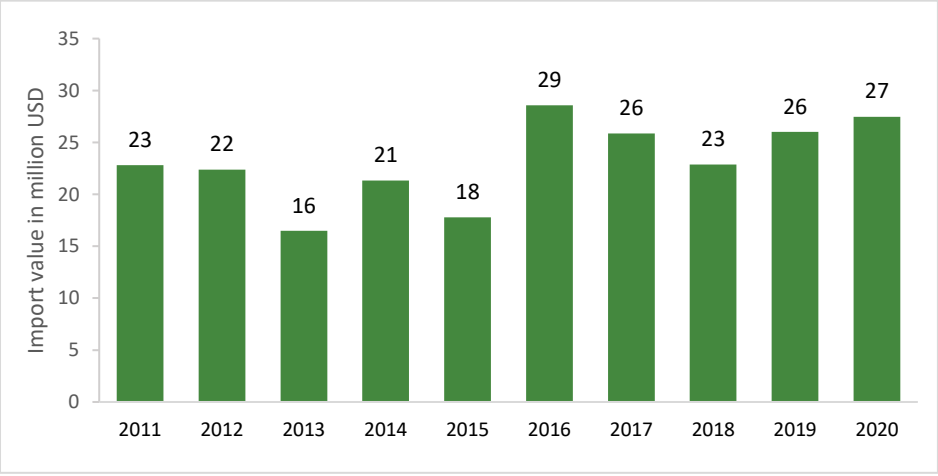


Figure 39: Tanzania import values of laboratory equipment (2011 – 2020, million USD)[122]

[121] UN Comtrade,2021
[122] UN Comtrade,2021

Unlike its neighbours, Tanzania's medical equipment imports in 2020 were not influenced by the COVID-19 pandemic since the government did not acknowledge its seriousness and prematurely declared victory over the pandemic. X-ray related apparatuses were the most imported medical equipment in 2020 and have been growing at a CAGR of 25.7% since 2012, which was the highest growth rate among all medical equipment. This is expected to be the trend in the next several years as imaging was identified as a key area of investment by health players in Tanzania.

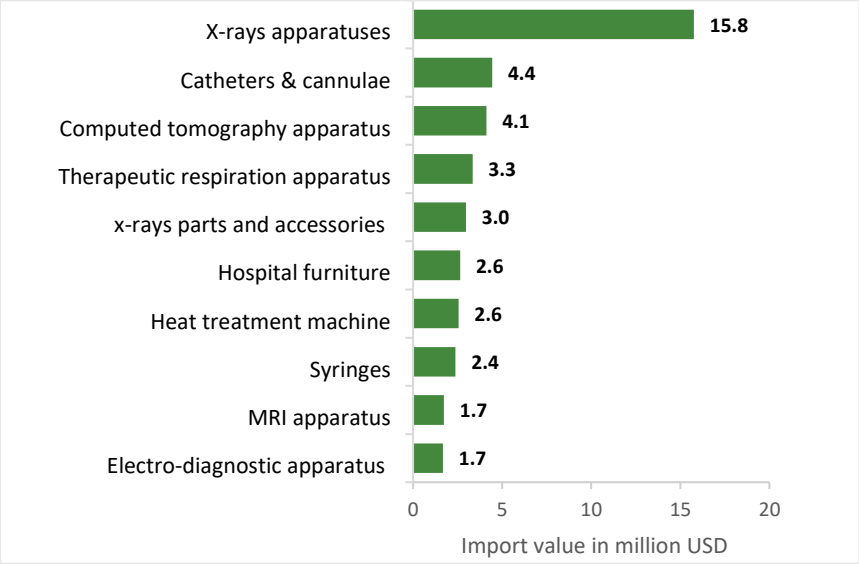


Figure 40: Tanzania top 10 medical equipment imports (2020, million USD)[123]

Optical radiation apparatuses and microtomes were the top laboratory equipment imports in 2020. They have also been the fastest growing product segments since 2012, recording a CAGR of 20.1% and 13.3% respectively. They are expected to remain the leading laboratory equipment imports for the next five years.

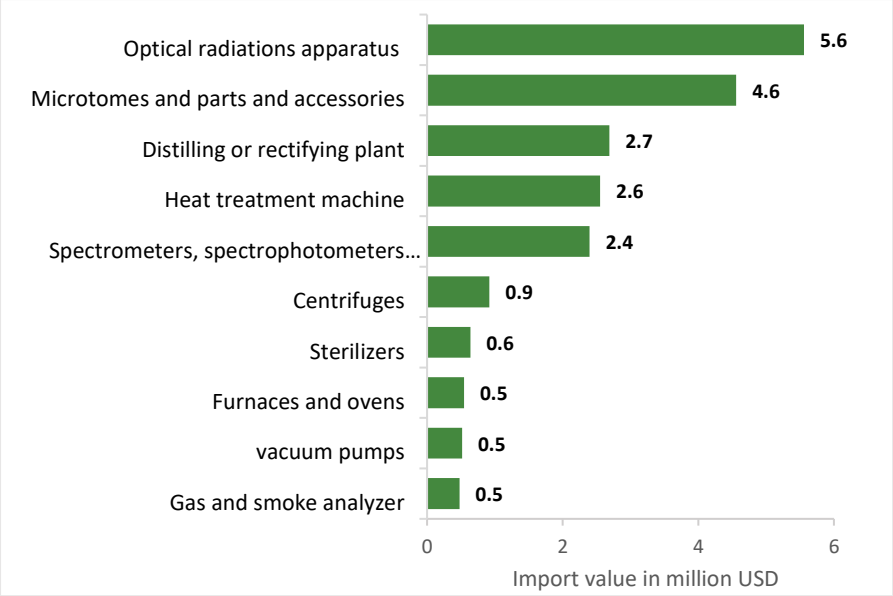


Figure 41: Tanzania top 10 laboratory equipment imports (2020, million USD)[124]

[123] UN Comtrade,2021
[124] UN Comtrade,2021

China is by far the leading source imports for medical equipment with about 34% of market share. Various western countries combined account for a market share of 34%.

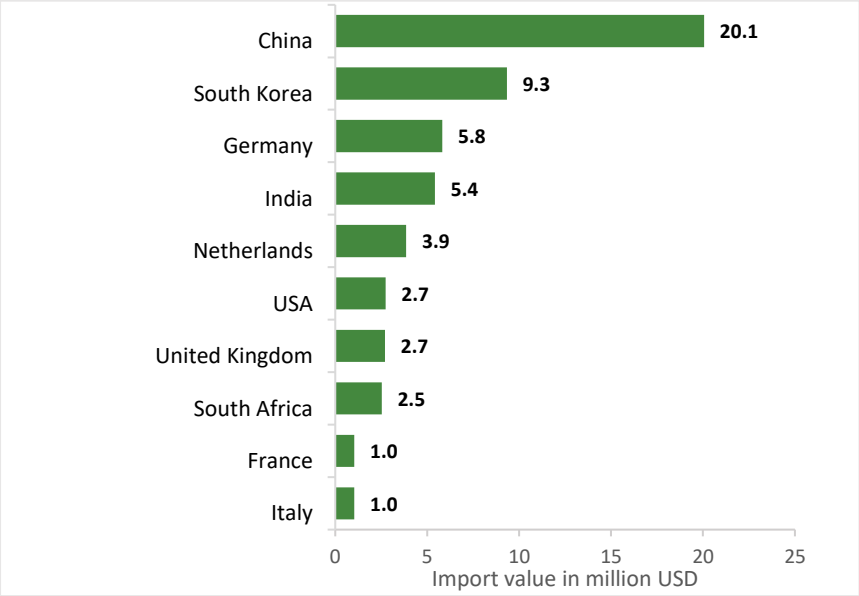


Figure 42: Origin of medical equipment imports in Tanzania (2020, million USD)[125]

China is the second most important source of laboratory equipment in Tanzania with a market share of 16%. The leading source of laboratory equipment imports is Germany with a market share of 21%. All western countries combined account for 58% of laboratory equipment imports.

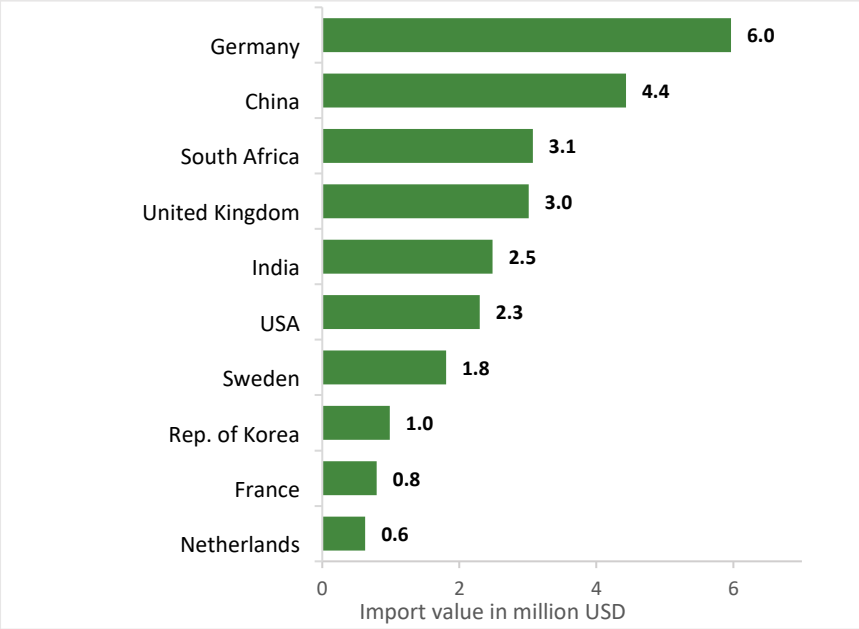


Figure 43: Origin of laboratory equipment imports in Tanzania (2020, million USD)[126]

[125] UN Comtrade,2021
[126] UN Comtrade,2021

4.3.3. Medical technology investment decision-making process – Tanzania mainland

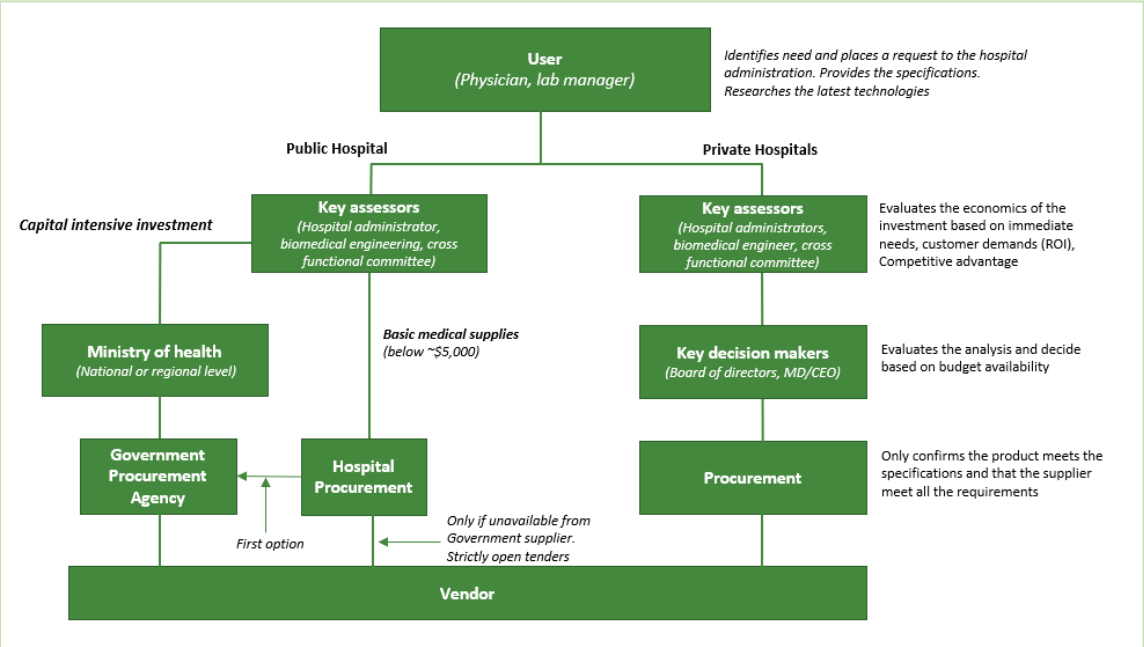


Figure 44: Medical and laboratory equipment investment decision making process in Tanzania (2021)[127]

The investment decision involves different stakeholders. Also depending on the capita intensity of the decision, several stakeholders would have to be consulted and permission sought for. Laboratory managers or respective heads of departments usually trigger the request for the purchase of medical and laboratory equipment products. At the public hospital level, requests usually go to the hospital administrators who evaluate the need for the product. If the decision to make the purchase is taken, the procurement department is tasked with purchasing the supplies from the MSD. On the other hand, capital intensive investments are opened for public tendering in case MSD does not stock the required products. In the private medical sector, key decision-makers are the chief executive or board of directors of the hospital.

Purchasing criteria

From the research conducted by africon, hospitals and labs mentioned that pricing and quality were the most important purchasing criteria considered. For pricing, it is thus not surprising that China featured prominently in the top medical equipment supplier countries. Other criteria considered were brand familiarity and references from industry experts. In the public sector, procurement is done through open tendering which means product specifications are more important compared than brand names. Single sourcing only happens in the private sector where preferences to certain brands is a bigger factor

Source of information for medical technology equipment

According to research conducted by africon across the health sector in Tanzania, all healthcare facilities confirmed to have learnt about new medical technology via direct contact with vendors.

[127] africon research, 2021

Another popular way hospitals learn about new technologies is through colleague recommendation and online resources. Conferences and trade shows were found to be the least popular way to learn about new technology. Reasons were a lack of funding to attend international events, especially in the public sector and they were described as time consuming.

4.3.4. Medical and laboratory equipment regulation – Tanzania mainland

The Tanzania Medicines and Medical Devices Authority (TMDA) is the National Regulatory Authority established to regulate quality, safety and effectiveness of medicines, medical devices, diagnostics, biocidal and tobacco products.[128]

According to TMDA, medical devices refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is:

a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
c) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

Import process

All medical devices to be imported into Tanzania must be registered by the Tanzania Medicines and Medical Devices Authority (TMDA) unless given special approval by the Authority. In order to register a device, a cover letter, duly filled application form, referenced literature and two samples of the products need to be submitted to TMDA. For devices with European certification (CE), the declaration of conformity from the manufacturer must be submitted, in addition to the EC certificate issued by the relevant body. Once an application has been accepted, the processing of application takes between 90 to 240 calendar days. The registration of a medical device is valid for five years unless suspended or revoked by TMDA or terminated by the registrant.

Once registration is done, the importer can apply for an import permit. Importation can only be done by importers whose premises are dully registered by TMDA. A registered importer applies for an import permit by filling an application form which should be accompanied by a proforma invoice. Once submitted to TMDA, all applications are processed within twenty-four hours during working days with exception of special requests which may take longer period. An Import permit is valid for six months and is not transferable and is issued to cover only one shipment. All importers are required to hold a valid importation permit issued by the Authority prior to shipping of the consignment.

Before shipping to Tanzania, medical devices are subject to Pre-shipment Verification of Conformity (PVoC) and therefore must obtain the mandatory custom clearance documents and certificate of conformity (CoC) without which the commodities arriving at Tanzanian Ports will be rejected or fined. PVoC is carried out by authorized third-party agencies appointed by the Tanzania Bureau of Standards (TBS) who include SGS and Bureau Veritas.

On arrival at the ports of entry, medical devices will be inspected by a TMDA Inspector to ensure that they comply with the approved specifications and regulations before they are released. Each consignment must be accompanied by an import permit, an original proforma invoice, a

[128] Tanzania Medicines and Medical Devices Authority (TMDA) 2021

corresponding certificate of analysis for each batch and airway bill or bill of lading. Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Tanzania Revenue Authority (TRA) or other authorized agents. At the time of importation, medical products must have a valid shelf life not less than 60 % of the original shelf life.

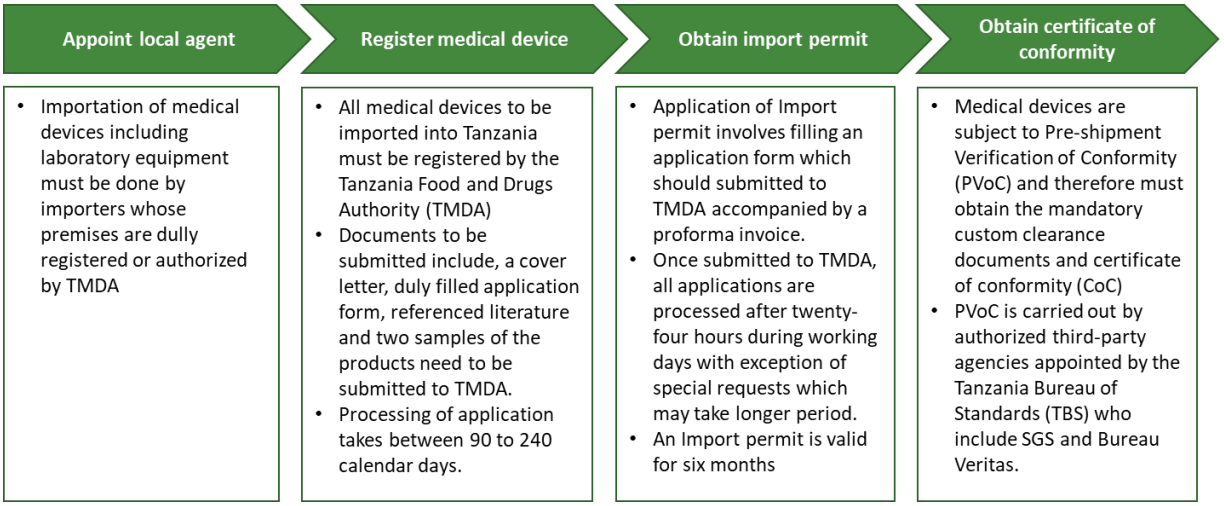


Figure 45: Tanzania medical and laboratory equipment import process (2021)[129]

[129] africon research 2021

4.3.5. E-health in Tanzania mainland

The state of e-health in Tanzania

Although there has been an increasing adoption of e-health in Tanzania, just a handful of health facilities have implemented it. It was estimated that there were about 128 e-health system operational in Tanzania as of 2017[130]. These included electronic health records system, mobile health (m-health) and telehealth. Only few of these facilities are actually leveraging the full power of e-health, with majority of them only using the system for capturing patient's records.

E-health adoption challenges

The implementation of e-health has been limited by several challenges. Notable is the inadequacy and unavailability of necessary ICT infrastructure, particularly in rural areas. Furthermore, systems available do not have interoperability capacities. This results in poor and inconsistent data from multiple sources. There is a lack of a e-health governance structure, leading to the implementation of similar initiatives by different stakeholders. Inadequate skills and knowledge by end users who are expected to use these systems are another hurdle.

E-health policies

The Government of Tanzania is committed to improving the application of digital health technologies in order to facilitate attainment of her overall objective of delivering high-quality health services to all citizens. For this reason, the government developed The National Digital Health Strategy 2019–2024, which outlines how Tanzania intends to leverage digital health technologies. The goal of the strategy is to accelerate increased access to, as well as improved quality of effective and efficient healthcare to all Tanzanians through digitally enabled transformation of the health system. Some of the strategic priorities include better coordination and implementation of digital health initiatives, improving accessibility (including use of tele-health), improving health workforce competency in the use of technology, enhancing seamless and secure information exchange, improving supply chain management of health commodities, improving management of human resources and improving management of financial resources.

4.3.6. E-learning in Tanzania mainland

Health training landscape

Tanzania has about over 120 recognized health training institutions hosting various class sizes and cadres of healthcare workers[131]. Of these, at least 56 are government-owned, with the rest being a mixture of privately owned as well as faith-based intuitions.[132]

Health training is not limited to the classroom, but majority of programmes require practical training as part of their curriculum. The level of practical curriculum depends on the type of training. Certificate courses have the largest portion (70%) of their curriculum held as practical training, followed by diploma with 50% practical. Advanced programmes including graduate diploma and undergraduate degree have the least amount of practical training at about 30% of the curriculum.

E-learning in health training

[130] Hamad Wahid (2019), Current Position and Challenges of E-health in Tanzania: A review of literature
[131] Afya directory, 2021
[132] Ugwire, 2021

E-learning is yet to be widely adopted in health training. While the number of e-learning programmes has been increasing within Tanzanian teaching institutions, the COVID-19 pandemic made it imperative to enhance e-learning platforms to avert any future delays in study completion at universities. E-learning is not a new phenomenon in Tanzania as the Open University of Tanzania has been offering its study programmes purely by distance-learning mode since its establishment in 1992.

However, according to our research across health training institutions in Tanzania, the roll out of e-learning has not been without its challenges. All the surveyed institutions seemed to face similar issues including instructors who do not have the skills to teach online, scarce electronic content, a lack of internet connectivity, limited access to computers, students with limited computer literacy, and frequent electricity blackouts. Additionally, each institution operates its own learning management system (LMS) which has led to the duplication of time, money, and effort. There are efforts to have an integrated online platform that would make it easier for participation and quality assurance regardless of the institution.

The same institutions however confirmed that e-learning provided the benefit of teaching to a larger group of students despite the low number of teaching instructors.

5. Rwanda

5.1. Country profile - Rwanda

Geography

Rwanda is a landlocked state in East Africa surrounded by Uganda, the Democratic Republic Congo, Burundi, and Tanzania. With a population of around 12.6 million (growing by 2,64% per year on average in the past 5 years) and an area of 26,338 km², Rwanda is one of the countries with the highest population density on the African continent (with close to 500 inhabitants per km²)[133]. The capital Kigali lies in the geographic centre of Rwanda and is considered as the hub of economic and political life. Despite a positive development since the genocide in the early 1990s, Rwanda is considered a low-income state and ranks 160th of 190 countries on the Human Development Index.[134]

Social situation

Rwanda's population of 12.6 million is almost six times larger today than 60 years ago during the final years of colonial rule. 80% of the population lives in rural areas and works in agriculture. The 20% of urban population mainly work in social services, transport and trade, construction and utilities, finance, and real estate. Further jobs in light industry are emerging, particularly through foreign private investments. [135]

Despite the impressive growth Rwanda has had over the years, it remains a very poor country, where about half of the population lives below the national poverty line. However, absolute poverty has fallen from 77% in 2001 to 55% in 2017.[136] Rwanda has the highest inequality rate in East Africa. The income of the richest 10% is over 3 times higher than that of the poorest 40%. However, the Gini index as an indicator of inequality, has declined from 0.52 in 2006 to 0.43 in 2017. [137]

Even though Rwanda's ranking on the Human Development Index has stagnated at around 160 since 2005[138], local policies and initiatives contributed to significant social improvements and progress in healthcare, literacy rate and gender equality. Hence, living standards have improved, as shown by the strong decrease in child mortality by two thirds since 2000 for instance. Further, life expectancy at birth improved from 29 in the mid-1990s to 69 in 2019. The under-five mortality ratio has fallen from 149.8 per 1000 live births in 2000to 34.3 per 1000 live births in 2019.[139]

An almost universal primary school enrolment has been reached and the literacy rate among adults grew to 73.2% in 2018. [140]

Economic situation

The Rwandan economy has been the regional growth leader of the East African Community for the past couple of years despite its landlocked location. Rwanda's economy grew at an average rate of 7.4% between 2015 to 2019 before Covid-19 hit. These numbers are remarkably higher than the Sub-

[133] World bank, 2021
[134] World bank, 2021
[135] BTI Transformation Index 2020
[136] World bank, 2021
[137] World bank, 2021
[138] BTI Transformation Index 2020
[139] World bank, 2021
[140] World bank, 2021

Saharan Africa average of 2.7%.[141] The Key driver of this impressive growth has been large public investments (12.3% of GDP in 2019)[142] in infrastructure like the new Bugesera International Airport and multiple mega road projects in and around the city of Kigali.

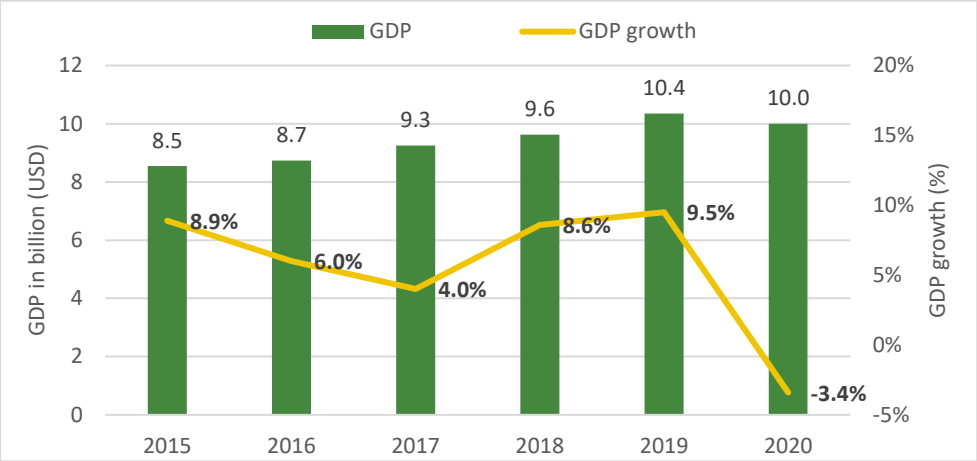


Figure 46: Rwanda GDP and GDP growth rate (2016 – 2020, Billion USD and % growth)[143]

However, in 2020, the Rwandan economy is estimated to have contracted by 3.4% because of the COVID-19 pandemic.

GDP composition

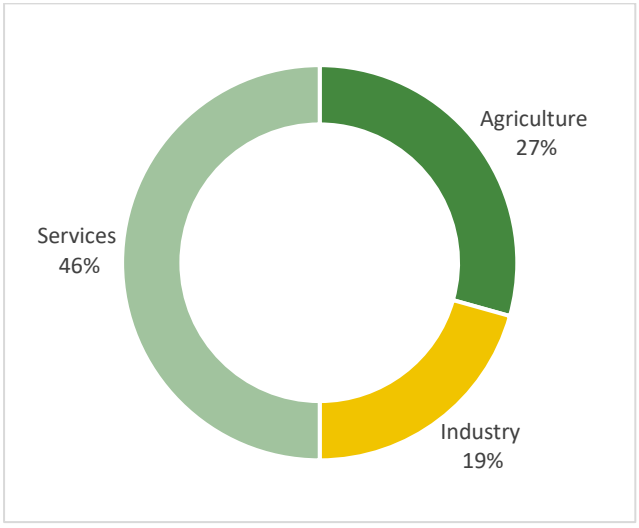


Figure 47:Rwanda GDP composition (2020, % of total)[144]

The three main sectors of the Rwandan economy are services, agriculture, and industry, which contributed 46%, 26% and 19% respectively to the overall GDP as per 2020 estimates.[145] The remaining 8% is attributed to adjustment for taxes less subsidies on products. Industry and services despite only employing 9% and 25% of the total workforce respectively, have become the leading engines of growth. However, agriculture remains the main source of employment.

[141] IMF, World Economic Outlook 2021
[142] World bank 2021
[143] National Institute of Statistics Rwanda 2021
[144] National Institute of Statistics of Rwanda, GDP National Accounts 2020
[145] National Institute of Statistics of Rwanda, GDP National Accounts 2020

COVID-19 impact

Rwanda was in the middle of an economic boom prior to the COVID-19 pandemic. Economic growth in 2019 was one of the highest in the world at 9.4% before declining sharply to -3.4% in 2020. Trade, transportation, and tourism services were the most affected sectors as strict measures were put in place to prevent the spread of the virus. Hotel and restaurant activity dropped by 40%, followed by education (-38%) and transport activities (-24%).[146] Wholesale and retail trade and construction were less severely impacted. Information and communication even grew by 29%. The health sector grew by 19% due to among others, efforts taken in containing the COVID-19 pandemic.[147]

Outlook

Growth is projected to rebound in 2021 and 2022, supported by high infrastructure spending on Bugesera International Airport and a pick-up in the tourism sector as the effects of the pandemic dissipate. The implementation of the African Continental Free Trade Area is expected to boost intraregional trade, which would support growth, especially if Rwanda increased its share of intraregional exports. The current rollout of COVID–19 vaccines should trigger a rebound in tourism and foreign direct investment. The downside risks to the outlook include trade disruptions due to simmering regional political tensions especially with Uganda and a resurgence of the COVID–19 virus.[148]

[146] National Institute of Statistics of Rwanda, GDP National Accounts 2020
[147] National Institute of Statistics of Rwanda, GDP National Accounts 2020
[148] AfDB, Rwanda Economic Outlook 2021

5.2 Overview on the health sector - Rwanda

5.2.1 Healthcare system - Rwanda

In May 2000, the Government of Rwanda adopted the national decentralization policy as a means of promoting of good governance, reducing poverty and improving the efficient, effective, and accountable delivery of services. One of the priority areas in the decentralization efforts was the health sector. Rwanda adopted a health development strategy based on decentralized management at district level. Under this system, the Ministry of Health was restructured to assume reduced roles of health policy formulation, standard setting, technical support, regulation, supervision and inspection. The district health system was restructured to enable it to take on enhanced roles. The district health offices operate as autonomous entities, providing services to well-defined populations in either urban or rural zones. The district health offices are responsible for the health needs of the population in that zone and for the health facilities and services, whether provided through the governmental or private sector. The planning and management of primary health sector takes place at the district and lower levels with the involvement of the communities.

Health infrastructure

Rwanda has a total of 1,954 registered health facilities. 85% of these facilities are Government owned, while 15% are Privately owned.[149] The private health sector in Rwanda is small and concentrated in the capital, Kigali. It is diverse and constitutes commercially operated private hospitals, polyclinics, NGO operated facilities, and faith-based hospitals.

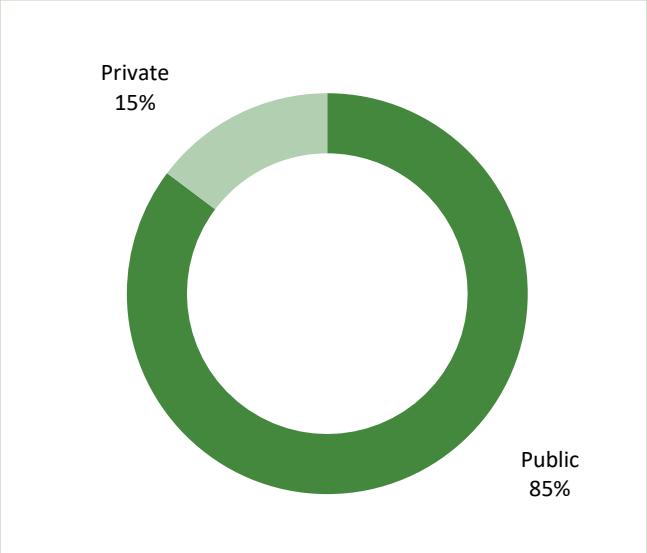


Figure 48: Ownership of health facilities in Rwanda (2020, % of total)[150]

The Rwandan health system follows a hierarchical structure starting with services offered by community health workers at the village level moving up to health posts/centres, district/provincial hospitals, and ending with referral/teaching hospitals at the national level.

Generally, the service package at a district hospital includes inpatient / outpatient services, surgery, laboratory services, gynecology-obstetrics, radiology, mental health, dental and eye services. The health centres provide preventive services, primary healthcare, in-patient care, referrals, and basic maternity services, while the health posts provide services such as immunization, family planning, growth monitoring, and antenatal care.

[149] MOH, Rwanda Health Sector Performance Report 2019-2020
[150] MOH, Rwanda Health Sector Performance Report 2019-2020

At the village level, Community Health Workers (CHWs) provide prevention, promotion and some curative health services.

As of June 2020, the national health facility density stood at 0.15 per 1,000 population, which is below WHOs recommended target of 0.2 per 1,000.

Level of health facility	Number of facilities
National Referral Hospital	8
Provincial Hospital	4
District Hospital	37
Health Centre	510
Prison Clinic	13
Health Post	1,094
Private Dispensary	122
Private Clinics and polyclinic	158
Private Hospital	8
Total	**1,954**
Ratio per 1,000 population	**1.5**

Table 10: Health facilities by level in Rwanda (2020)[151]

Health workforce

Rwanda has a shortage of health workers. As of June 2020, there were 1,518 doctors working in both private and public health facilities (including 493 specialists and 1,025 general practitioners), 10,447 nurses and 1,562 midwives.

Although there is a shortage in human resources for health, there has been a steady improvement over the past decade from 0.06 doctors per 1,000 people in 2010 to 0.12 doctors per 1,000 people in 2020. Nurses per 1,000 population ratio has also improved from 0.77 nurses per 1,000 people in 2010 to 0.83 nurses per 1,000 people in 2020.[152]

The national density of doctors, nurses and midwives in 2020 stood at 1.08 per 1,000 population, which is below WHO's recommend minimum of 4.45 health workers per 1,000 population.

Type of health worker	Number of health workers	Ratio per 1,000 population
Medical Doctor	1,518	0.12
Nurse	10,447	0.83
Midwife	1,562	0.12
Total	**13,527**	**1.08**

Table 11: Health workforce in Rwanda (2020)[153]

[151] MOH, Rwanda Health Sector Performance Report 2019-2020
[152] MOH, Rwanda Health Sector Performance Report 2019-2020
[153] MOH, Rwanda Health Sector Performance Report 2019-2020

5.2.2 Healthcare expenditure - Rwanda

Healthcare spending in Rwanda comes from three main sources – public, private, and external sources. Private spending accounts for the largest share of healthcare expenditure accounting for 38% of total healthcare spending. This is mainly attributed to the popularity of community-based health insurance (CBHI), a voluntary scheme where community members pool funds to offset the cost of healthcare. Rwanda is also heavily reliant on external financing to meet its health needs with 31% of total expenditure coming from external sources which is equivalent to its public healthcare spending.

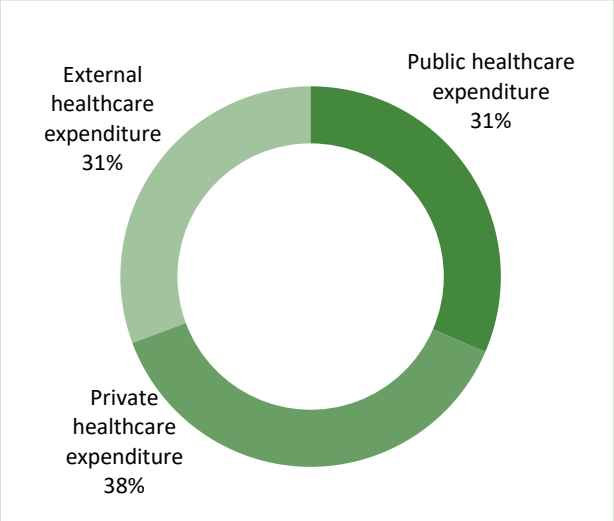


Figure 49: Rwanda Health expenditure by source (2018, % of total)[154]

Health expenditure per capita has seen a marginal increase between 2011 and 2018 from USD 53 per capita to USD 58 per capita. However, it has not kept up with GDP with the health expenditure ratio to GDP dropping from 8.2% in 2011 to 7.5% in 2018.

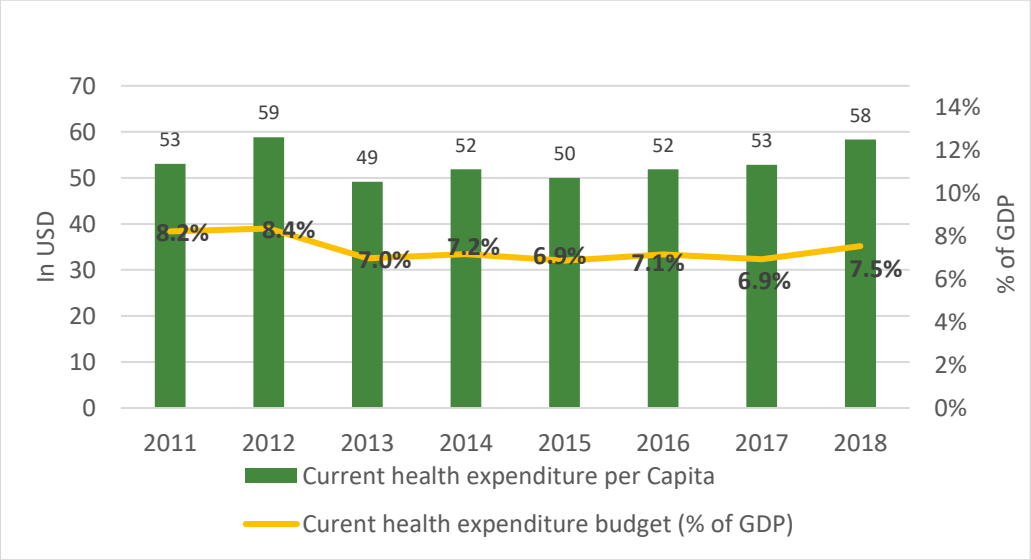


Figure 50: Rwanda current healthcare expenditure (2011-2018, per capita and as % of GDP)[155]

[154] World bank 2021
[155] World bank 2021

Government budgetary allocation to the health sector has seen a steady increase over the past five years going from USD 188 million in the 2016/17 to USD 254 million in 2020/21.[156]. However, the health budget as a share of total national budget has been declining, dropping from a high of 9.7% in FY 2016/17 to a low of 7.8% in FY 2020/21.

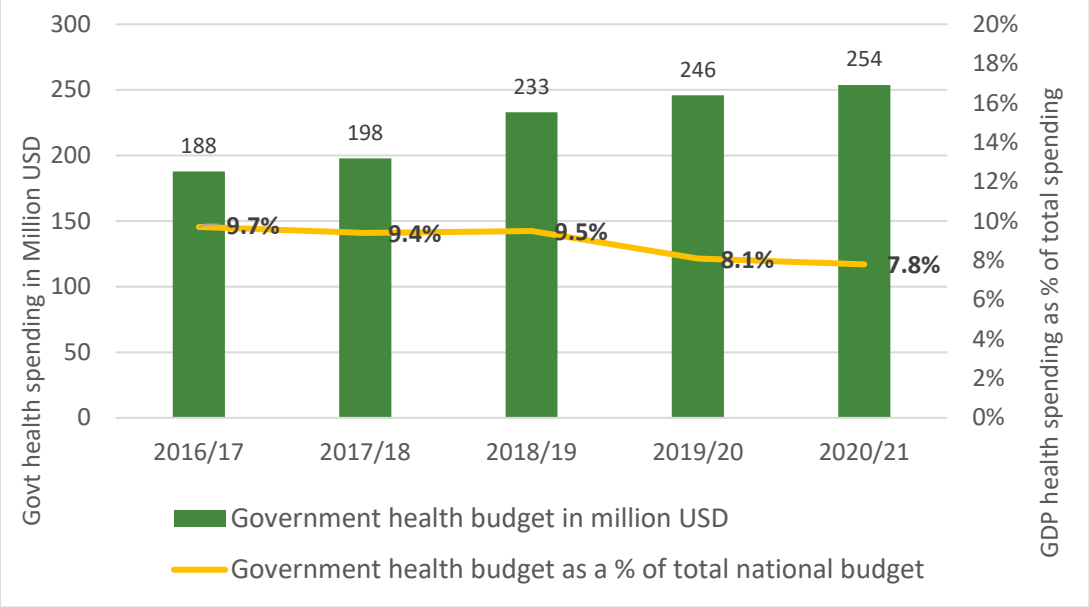


Figure 51: Rwanda health budget and its share of total national budget (2016 – 2021, million USD and % growth)[157]

5.2.3 Disease burden and trends - Rwanda

Rwanda faces a double burden to its health system by having to not only deal with infectious diseases that have historically plagued the country, but also address the rise of non-communicable diseases (NCDs). This rise in the burden of NCDs is associated with demographic and social changes such as globalization, urbanization, and adoption of unhealthy lifestyles such as consumption of unhealthy diets, physical inactivity, and excessive alcohol consumption.

	Top 10 diseases causing death 2009		Top 10 diseases causing death 2019	% change in deaths 2009-2019
1	Neonatal disorders	1	Lower respiratory infections	-17.7%
2	Lower respiratory infections	2	Neonatal disorders	-18.2%
3	HIV/AIDS	3	Stroke	41.1%
4	Diarrheal diseases	4	Tuberculosis	-14.5%
5	Tuberculosis	5	Ischemic heart diseases	56.9%
6	Malaria	6	Diarrheal diseases	-31.4%
7	Stroke	7	Malaria	-11.2%
8	Ischemic heart diseases	8	HIV/AIDS	-52.8%
9	Congenital defects	9	Cirrhosis	33.8%
10	Cirrhosis	10	Congenital defects	-17.7%

[156] UNICEF, Rwanda Health Budget Brief 2020-2021
[157] UNICEF, Rwanda Health Budget Brief 2020-2021

Table 12: Top 10 diseases causing deaths in Rwanda (2009, 2019, % change)[158]

Between 2009 and 2019, lower respiratory infections and neonatal disorders remained the two top leading causes of deaths despite recording a decline in death numbers by -17.7% and -18.2% respectively. During the same period, only stroke, ischemic heart diseases and cirrhosis saw a positive increase in death incidences. All three conditions are non-communicable and lifestyle related diseases. This is a clear demonstration that non-communicable diseases are going to present great health concerns going forward.

Rwanda has made great progress in fighting HIV/AIDS, which dropped from third to eighth largest cause of death between 2009 and 2019. This has mainly been through sensitization efforts by both the local government and donors. Tuberculosis, despite recording a decline in death incidences, rose from fifth to fourth position between 2009 and 2019. Malaria also saw a decline in death incidences by 11.2%, but only drop one spot from sixth to seventh.

Neonatal deaths declined by 18.2% between 2009 and 2019 but it remains a leading cause of death. Birth complications, sepsis, congenital abnormalities, diarrhoea, and pneumonia are among the leading causes of neonatal deaths.

This rise of non-communicable diseases (NCDs) expected to result in an increasing demand for new medical equipment and technology for diagnosing and managing emerging chronic diseases such as cardiovascular diseases.

[158] IHME, 2019

5.3. Medical and laboratory equipment landscape - Rwanda

5.3.1. Medical and laboratory equipment value chain - Rwanda

Rwanda has no local production of medical and laboratory equipment and therefore all medical supplies are imported.

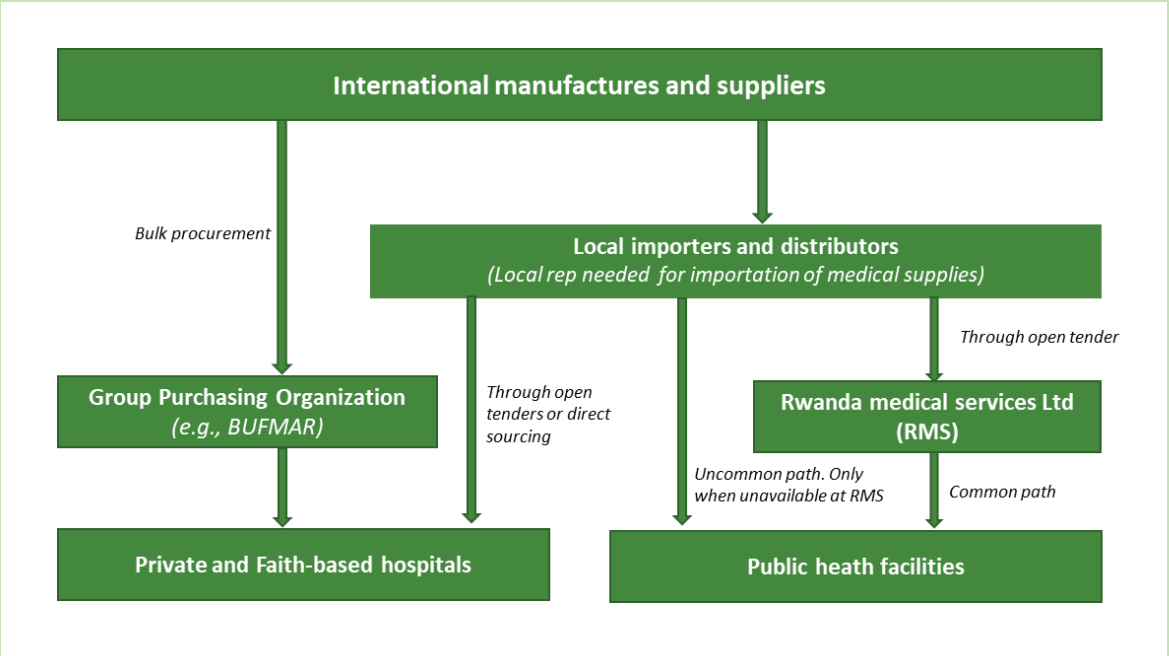


Figure 52: Rwanda medical and laboratory equipment value chain (2021)[159]

Public sector

Rwanda Medical Services (RMS) is the procuring agency in Rwanda mandated by the Rwandan government to provide quality, reliable and affordable pharmaceutical products for all public health facilities in Rwanda. This includes medical equipment, consumables, medicines, and laboratory commodities. It gets its funding from the government (90%) and donors (10%). RMS has a priority over other private distributors when it comes to selling to public health facilities. By law, public health facilities are obligated to first purchase from RMS and only if unavailable can they source from private distributors.

Private sector

In the private sector, procurement of medical supplies is done either through independent distributors or group purchasing organizations. The main group purchasing organization in Rwanda is the Bureau des Formations Médicales Agréées du RWANDA (BUFMAR), a non-governmental organization created in 1975 by Christians with the objective of procuring and distributing quality pharmaceutical products and medical equipment to faith-based health facilities. They eventually expanded their market reach to also supply public hospitals when stock is unavailable from RMS as well as commercially operated private hospitals. BUFMAR sources directly from manufacturers. BUFMAR leverages the combined purchasing power of members to negotiate favourable contract pricing from suppliers.

[159] africon research, 2021

5.3.2. Import trends of medical and laboratory equipment - Rwanda

Imports of medical equipment grew by only 20% between 2011 and 2020, from USD 15 million to USD 18 million. Imports are expected to maintain the moderate pre-pandemic CAGR of 2% in the next five years.

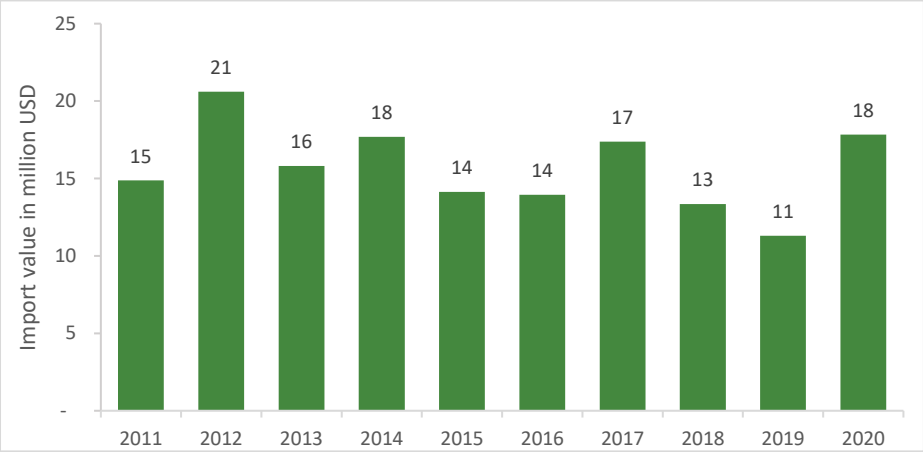


Figure 53: Rwanda import value of medical equipment (2011 – 2020, million USD)[160]

Laboratory equipment imports have been inconsistent over the past decade and in 2020 declined to their lowest level in 10 years. Imports are expected to hover between USD 4 million and USD 9 million for the next 5 years.

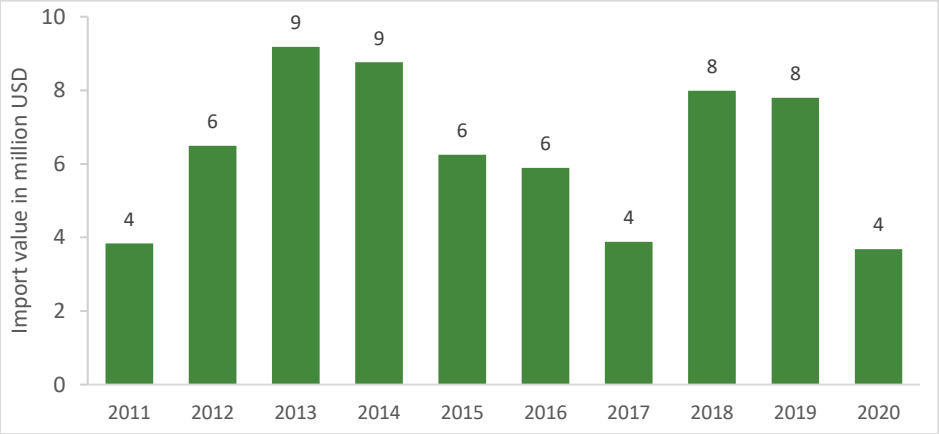


Figure 54: Rwanda import value of laboratory equipment (2011 – 2020, million USD)[161]

Therapeutic respiratory apparatuses saw the highest demand in 2020 due to the COVID-19 pandemic. Respiratory problems were the main complication faced by COVID-19 patients and therefore breathing aid devices were needed to support the patients with acute respiratory problem due to pneumonia associated to COVID-19. However, with COVID-19 cases declining significantly in 2021, imports are expected to drop below pre-pandemic levels as most hospitals will be left with excess capacity built up during the height of the pandemic.

[160] UN comtrade, 2021
[161] UN comtrade, 2021

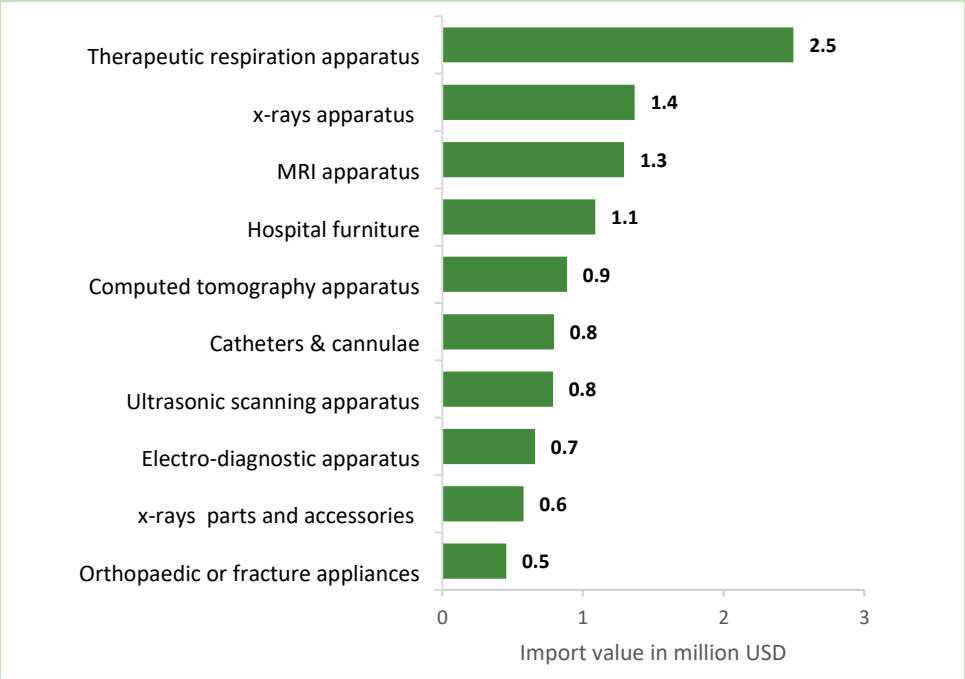


Figure 55: Rwanda top 10 medical equipment imports (2020, million USD)[162]

Spectrometers, microtomes, and optical radiation apparatuses were the top three laboratory equipment imports in 2020 and this has been consistent over the past decade. Rectifying plants, gas analysis apparatuses and spectrometers were the fastest growing product segments between 2012 and 2020, increasing by 567%, 266% and 204% respectively.

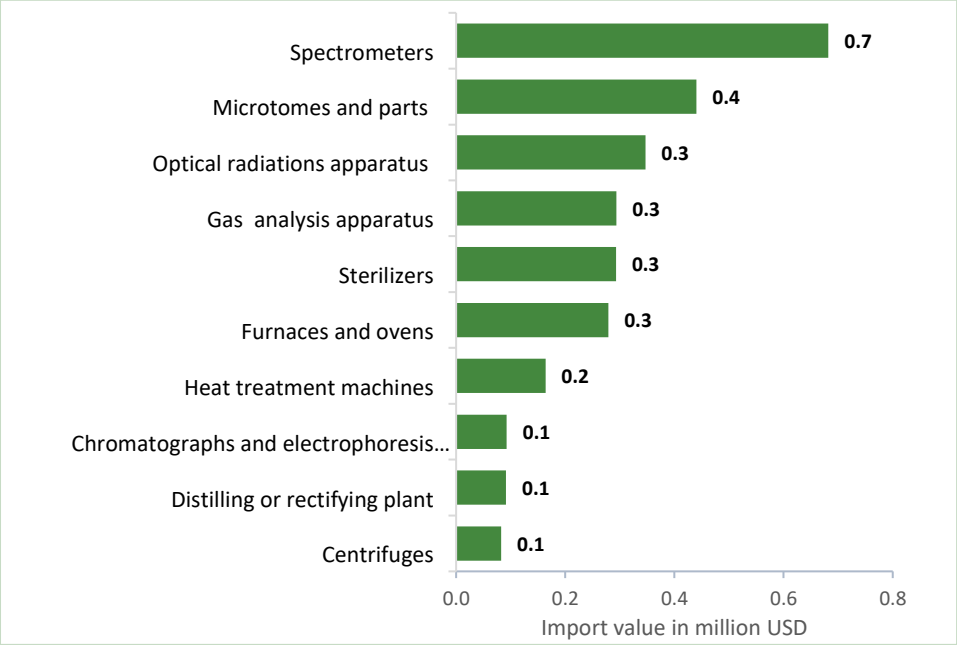


Figure 56: Rwanda top 10 laboratory equipment imports (2020, million USD)[163]

[162] UN comtrade, 2021
[163] UN comtrade, 2021

China is the leading source imports for medical equipment with about 24% of market share followed closely by Belgium which has a market share of about 22%. Western countries have a combined market share of 61%.

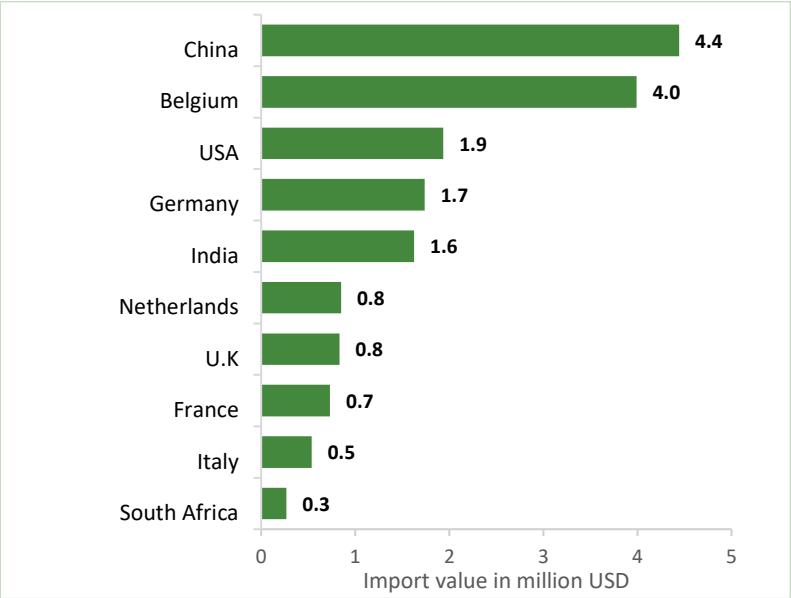


Figure 57: Origin of medical equipment imports in Rwanda (2020, million USD)[164]

China is also strong in the laboratory equipment segment with a market share of 13% and is the third largest source of laboratory equipment in Rwanda after India and Germany with market shares of 15% and 13% respectively. Western countries combined account for 61% of laboratory equipment imports.

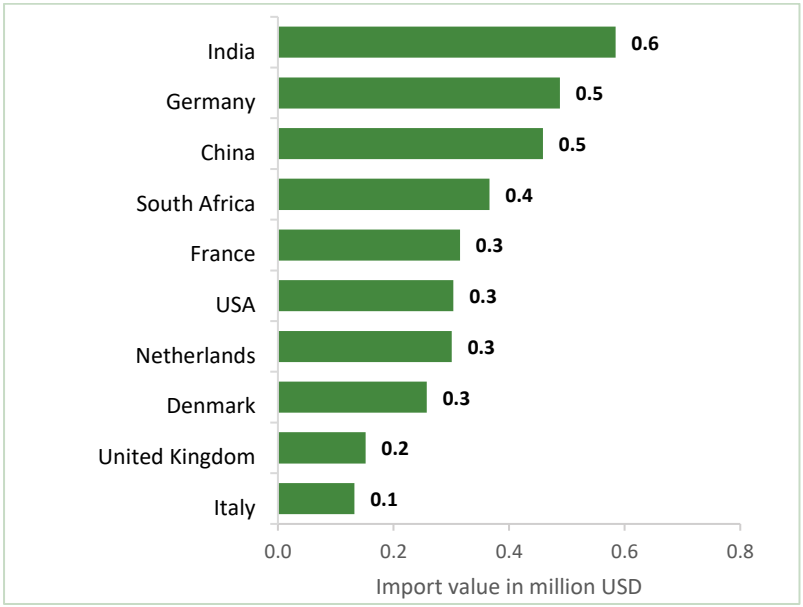


Figure 58: Origin of laboratory equipment imports in Rwanda (2020, million USD)[165]

[164] UN comtrade, 2021
[165] UN comtrade, 2021

5.3.3. Medical and laboratory equipment investment decision-making process - Rwanda

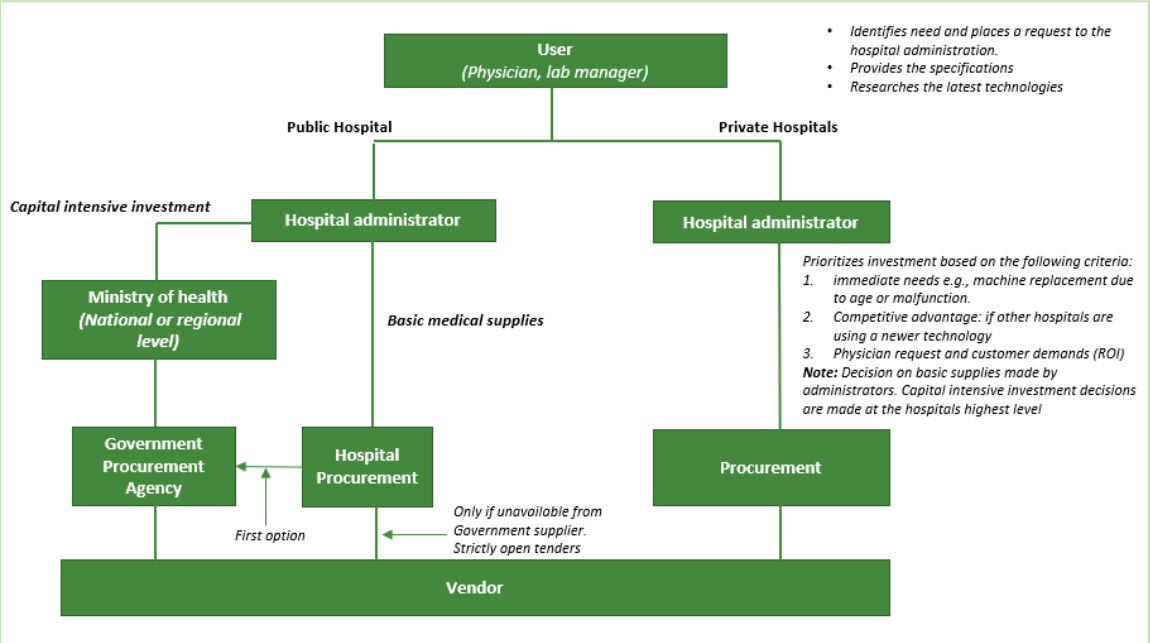


Figure 59: Medical and laboratory equipment investment decision-making process in Rwanda (2021)[166]

The capital investment decision process on medical technology involves various parties such as the procurement officer, technical team, government procurement agency and the hospital management who makes the overall decision as to which medical technology should be invested in. The decision is made based on a variety of factors such as patients' demands, estimated rate of return and affordability. The hospital management will analyse these criteria and ultimately determine whether to get the technology or not. The process of acquiring a medical technology usually starts from the user putting forward a request for the equipment to the hospital administrator. If the hospital management decides to purchase that equipment after deliberation, the procurement process begins through the procurement department.

For the public sector, the procurement of all medical and laboratory equipment is handled by the government procuring agency Rwanda Medical Supply (RMS). The medical suppliers are sourced through open tenders. However, in the private sector, procurement can take place either through single sourcing from a particular supplier or through open tenders.

Purchasing criteria

Based on the research conducted by africon, hospitals and labs surveyed mentioned that pricing and quality were the most important purchasing criteria considered. For pricing, it is thus not surprising that China featured prominently in the top supplier countries of medical and laboratory equipment. Other criteria considered were brand familiarity. Despite procurement in the public sector being done strictly through open tenders, new unknown players have to prove their reliability even if they meet all the specifications. Single sourcing only happens in the private sector where preferences to certain brands is a bigger factor.

Source of information for medical technology equipment

[166] africon research, 2021

Based on the research conducted by africon, the most common way healthcare providers in Rwanda learnt about new medical technology was via direct contact with vendors. Another popular way hospitals learn about new equipment was through online resources. Conferences and trade shows were relatively popular compared to other East African countries as Rwanda is fast becoming a MICE (Meetings, Incentives, Conventions, Exhibitions) hub.

5.3.4. Medical and laboratory equipment regulation - Rwanda

The Rwanda Food and Drugs Authority is the national regulatory authority established under the Ministry of Health mandated to regulate the registration and approval of medical products and health technologies in Rwanda. According to Rwanda Food and Drugs Authority, a medical device is defined as any instrument, machine, appliance, or material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, cure, surgery or for human or animal health protection.

Import process

A medical device must first be registered with the Rwanda Food and Drugs Authority (FDA) before it is imported into the country. An application for medical devices registration is made in writing via a cover letter and application form dated and signed by the applicant. The applicant should be an appointed local technical representative (LTR) of the manufacturer.

The local technical representative will also apply for an import authorization/visa which is issued by the Rwanda Food and Drugs Authority. To obtain an import authorization/visa, a proforma Invoice and proof of compliance to International Standards or European Community Standards (ISO or CE certificate) issued by a certified regulatory body are required. A medical device import authorization/visa is valid for a period of 3 months.

Unlike it East African neighbours, Rwanda does not have a Pre-export verification process (PVoC) process but instead conducts destination inspection at points of entry. This is done by the Rwanda Standards Board (RSB). The final commercial invoice, product registration number from FDA, packing list of the cargo, certificate of conformity from the manufacturer and certificate of origin will need to be presented during clearance and the imported will receive a verification certificate.

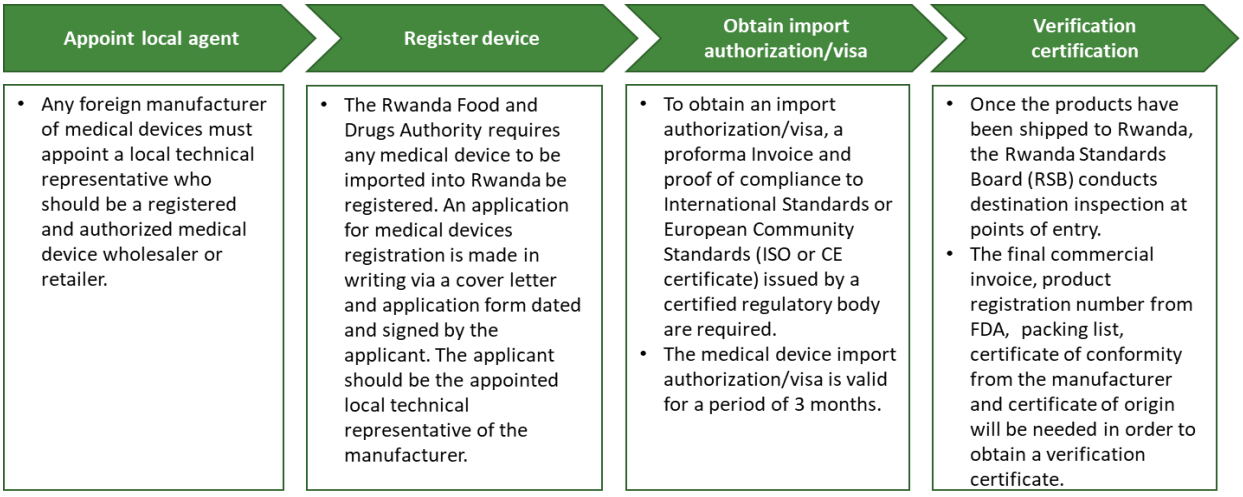


Figure 60: Rwanda medical and laboratory equipment import process (2021)[167]

[167] africon research, 2021

5.3.5. E-health in Rwanda

The state of e-health in Rwanda

Rwanda was a pioneer among African countries in developing an enterprise architecture for health and implementing the first proof of concept for a health information exchange through the Rwanda Health Enterprise Architecture Project (2010-2014). Health facilities in Rwanda have been using electronic medical records systems of one type or another for many years. Nearly 400 health centres have OpenMRS-based HIV case management modules, while about 10 hospitals have a more comprehensive 'full package' also developed in OpenMRS. At least 20 facilities are using OpenClinic at the hospital level with features similar to the full package.[168]

In 2020, the Government of Rwanda and Babylon Health (operating as Babyl in Rwanda) entered into a 10-year partnership to enable Rwandans countrywide to access quality healthcare services through their mobile phones. Through the partnership, Babyl will work with the Ministry of Health to develop a new healthcare delivery model called 'Digital-First Integrated Care', for convenient access to qualified doctors and nurses, especially for people living in remote areas.[169]

E-health adoption challenges

Unlike its neighbors, Rwanda is already way ahead in terms of e-health adoption. Rwanda has also addressed most of the barriers of e-health found in other East African countries, including stable power and internet. However, a few challenges still exist including low digital literacy rate especially in the rural areas. Even though Rwanda has addressed the issue of cost by using open-source software, hardware cost is still an issue.

E-health policies

Rwanda has developed the National Digital Health Strategic Plan 2018 – 2023 that outlines its plan to develop and implement digital health. This strategic plan builds on earlier successes by proposing strategies to scale up certain interventions at a national level and enhancing their performance to ensure that the systems meet users' needs. The strategic plan also proposes new information system interventions in order to automate the remaining services in the health sector.

The strategic plan emphasizes engagement of the private sector in form of public-private partnerships especially in activities related to software development and support as well as ICT infrastructure maintenance. Specific policy objectives of the plan include strengthening integration and interoperability of health information systems, improving collection, management and use of data at all levels of care, improving ICT infrastructure and software support in the health sector, as well as providing a legal framework for information security.

[168] MOH, Rwanda eHealth strategic plan 2018-2023
[169] RDB 2020

5.3.6. E-learning in Rwanda

Health training landscape

Health training institutions are very limited in Rwanda. Rwanda has one medical school, eight nursing schools, one dental school and one school of public health. The majority of Rwandan physicians are general practitioners, a term indicating that they did not complete a formal, post-graduate training programme a medical specialty. [170]This is due to inadequate post graduate training resources and limited financial capabilities from both the training institutions and health practitioners. The University of Rwanda College of Medicine and Health Sciences is the only academic training institution for physicians in Rwanda in which an average of 1,200 students enrol every year.[171]

E-learning in health training

E-learning is yet to be widely adopted in health training. Despite multiple institutions investing in digital resources to continue teaching online during COVID-19, Rwanda's Ministry of Education ordered schools to repeat courses taught online during closure period claiming unfairness to poor students who lacked the proper ICT tools and internet connectivity to access e-learning materials.[172]

According to our research across health training institutions in Rwanda, the roll out of e-learning has been challenging especially due to lack of necessary tools by students. Other challenges included instructors who don't have the skills to teach online, scarce electronic content and cost of internet.

The same institutions however confirmed e-learning provided the ability to teach bigger classes with a limited number of teaching instructors.

[170] MOH, 2021
[171] MOH, 2021
[172] The East African 2021

6. Zanzibar

6.1. Country profile - Zanzibar

Geography

Zanzibar is a semi-autonomous region within the United Republic of Tanzania. It lies in the Indian Ocean about 30 kilometers east of the Tanzanian coastline. It comprises two main islands, Unguja and Pemba, and a number of sparsely populated islets. It has a total area of about 2,654 square kilometers; of which 1,666 square kilometers are for Unguja island and 988 square kilometers are for Pemba. The spatial composition suggests that 68.8% of the population is in Unguja island while 31.2% is in Pemba.[173] Mjini Magharibi, a region in Ugunja, is considered the centre of attraction in all of Zanzibar and It is estimated host half of the Zanzibar population.

Social situation

Despite relatively high economic growth and progress on poverty reduction, the average incomes remain low in Zanzibar. Currently, poverty affects 25.7% of the population according to the latest household budget survey conducted prior to COVID-19.[174] Just over 10% of the population was extremely poor, with 11.4% of children living under the basic daily food consumption line.[175] At least two thirds of Zanzibar's children live in multi-dimensional poverty and experience high levels of deprivation insanitation, nutrition and housing.[176] Maternal, infant, and under five mortality rates are high at 155 (per 100,000 live births)[177] and 45 and 56 (per 1,000 live births)[178] respectively. Among children under 5, 21.5% are stunted. Whilst 89% of children enrol in primary school at the correct age, net enrolment rates for pre-primary and ordinary secondary education are much lower, at 48.8 and 44.8 per cent respectively.[179]

Economic situation

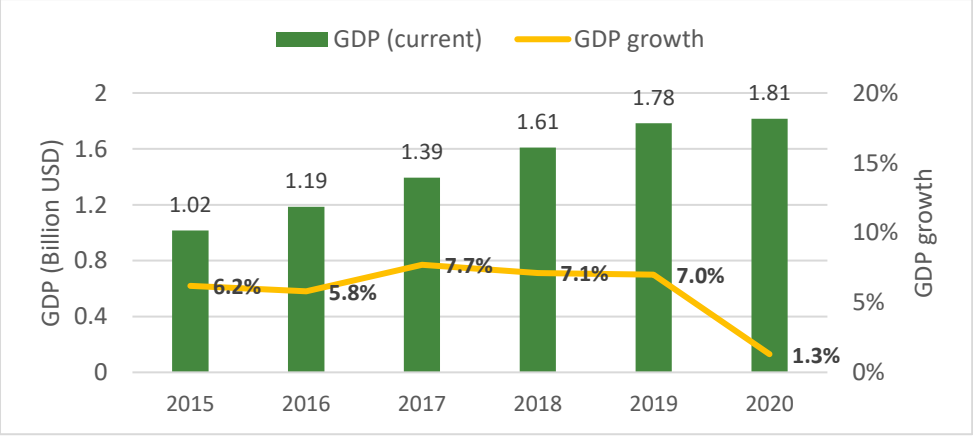


Figure 61: Zanzibar GDP and GDP growth rate (2015 -2020, Billion USD and % growth)[180]

[173] OCGS, Zanzibar statistical abstract 2020 – Pg.1
[174] OCGS, Zanzibar Household Budget Survey 2019/2020
[175] OCGS, Zanzibar Household Budget Survey 2019/2020
[176] OCGS, Child Poverty Report 2019
[177] UNICEF, Zanzibar budget brief 2019-2020
[178] UNICEF, Zanzibar budget brief 2019-2020
[179] Ministry of Education, Zanzibar Education Statistical Abstract 2016–2018
[180] OCGS, Zanzibar statistical abstract 2020 – Pg.88

Zanzibar's economy had been growing at a consistent rate of between 6% - 7% annually until 2019. However, 2020 saw a sharp decline as a result of the COVID-19 pandemic but Zanzibar was still able to record a positive growth of 1.3% while other countries saw a contraction. Zanzibar's economy is heavily dependent on the tourism sector which was one of the hardest hit sectors during the height of the pandemic.

GDP composition

The economy of Zanzibar Island is dominated by the agriculture and tourism sectors. Agriculture is a key sector of Zanzibar's economy in terms of food production, employment generation, production of raw material for industries and generation of foreign exchange. Cloves are the main cash crop with exports valued at roughly USD 16 million in 2020, accounting for about 40% of all goods exported. Watermelon and pineapples are the main fruits produced in the island accounting for 28.4% and 26% of the total fruits produced respectively.[181]

Tourism is Zanzibar's leading foreign exchange earner accounting for more than 80% of the total foreign exchange generated. Warm temperatures and white-sandy beaches attracted over half a million tourists annually to the region, mostly from European countries. Year-on-year tourist arrivals have been on the rise, increasing by an average of 15% over the last five years before the COVID-19 pandemic hit. The tourism industry is also a significant employer in Zanzibar, creating around 22,000 direct and 48,400 indirect jobs. Of the 22,000 direct jobs, approximately 16,720 persons (76%) are employed in the hotels and guest houses with the remainder employed in tourist restaurants, tourist shops, ground tour operators, airlines, and other tourism related.[182]

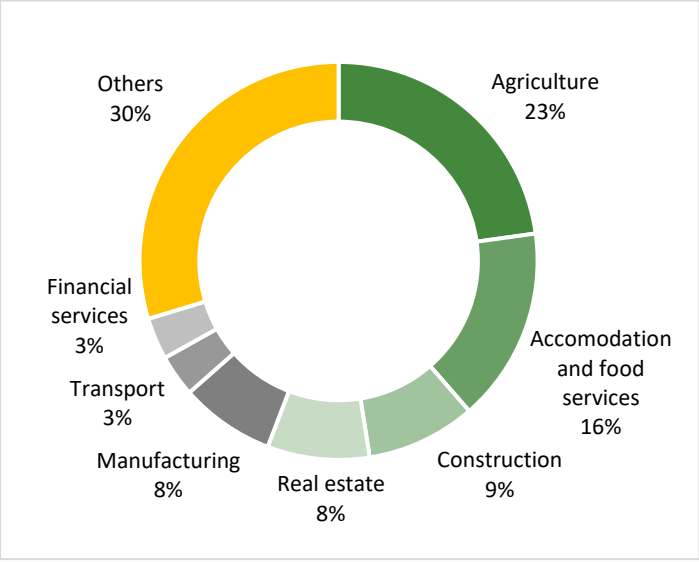


Figure 62: Zanzibar GDP composition (2020, % of total) 14[183]

COVID-19 impact

In the onset of COVID-19, most of the employees in the tourism sector lost their jobs following the shutting down of tourist hotels and cancellation of international flights. Tourist numbers recorded a sharp decline of over 50 percent from 538,264 in 2019 to 260,644 in 2020.[184]

[181] OCGS, Zanzibar statistical abstract 2020 – Pg. 107
[182] OCGS, Zanzibar statistical abstract 2020 – Pg. 142
[183] OCGS, Zanzibar statistical abstract 2020 – Pg. 90

Agriculture was also hard hit as low global demand and disruption of overseas logistics affected cloves export, which is Zanzibar's signature export item. Loss of jobs also had a dominos effect on local businesses as loss of income led to a drop in domestic demand.

Growth outlook

As of March 2021, Zanzibar's economy had already started registering moderate improvement with increased activities especially in the tourism sector. However, exports volumes are yet to go back to their pre-pandemic levels. [185]

The government, under its 5-year development plan (known as MKUZA IV) has committed to transform and diversify the economy of Zanzibar by fostering more productive sectors like manufacturing. This development is aimed at strengthening the economic resilience by reducing dependence on tourism, which has proven to be vulnerable as evidenced by the COVID-19 pandemic.

[184] OCGS, Zanzibar statistical abstract 2020 – Pg. 142
[185] The Exchange 2021

6.2 Overview on the health sector - Zanzibar

6.2.1 Healthcare system - Zanzibar

In 2002, Zanzibar initiated health sector reforms aimed at decentralizing the planning, prioritization, and integration of health services to the district level, while ensuring the availability of equitable high-quality healthcare services. As part of the decentralization efforts, the plan emphasized improvements in healthcare delivery at community-level facilities

Health infrastructure

The health infrastructure in Zanzibar is impressive when compared to the mainland and to other low -income countries in the region. A concerted effort by the Zanzibar government to ensure universal access to healthcare has resulted in 100% of the population being within 10km of a public health facility, and 95% within 5km.[186]

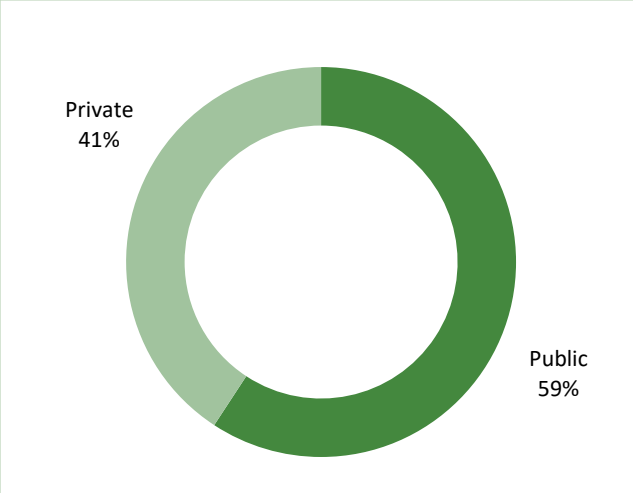


Figure 63: Ownership of health facilities in Zanzibar (2020, % of total)[187]

Zanzibar's public health system follows hierarchical structure. At the base are the dispensaries and health centres. At the community level are a network of first- and second-line Primary Health Care Units (PHCUs) which refer patients, as needed, to a smaller number of Primary Health Care Centres (PHCCs) and District Hospitals. For patients needing even more specialized care, they are referred to Mnazi Mmoja Hospital, the only tertiary level hospital on the island.[188]

The private sector also plays an important role in ensuring access to healthcare through absorption of demand from those able to pay. This significantly reduces waiting times at otherwise heavily over-subscribed public facilities, particularly in the urban areas. The number of private health facilities has been growing rapidly, especially dispensaries which increased from 70 units in 2013 to 113 units in 2020.

As of 2020, Zanzibar's health facility density stood at 0.17 per 1,000 population, which is below WHOs recommended target of 0.2 per 1,000.

[186] OCGS, Zanzibar statistical abstract 2020
[187] OCGS, Zanzibar statistical abstract 2020
[188] Ministry of Health, Zanzibar health sector reform strategic plan II 2006/07-2010/11

Level of health facility		Number of facilities
Primary level	**PHCU**	127
	PHCU+	33
	PHCC	2
Secondary level	**Regional Hospital**	1
	District Hospital	4
Tertiary level	**Special**	2
	Referral	1
Private hospitals	**Private Hospital**	4
	Dispensary	113
Total		**287**
Ratio per 1,000 population		**0.17**

Table 13: Health facilities by level in Zanzibar (2020)[189]

Health workforce

There is a severe shortage of healthcare workers in Zanzibar, particularly in hard-to-reach and remote areas. There are only 0.2 medical doctors for every per 1,000 people and this ratio is worse in poorer and more remote regions. There are also only 0.8 nurses per 1,000 people.

The number of health personnel is however on the rise in some of the cadres specifically medical doctors. The number of medical doctors has risen rapidly to reach 334 doctors in 2020 from only 29 doctors in 2013.[190] As of 2020, the density of doctors, nurses and midwives stood at 1.00 health workers (doctors, nurses and midwives) per 1,000 population, which is below WHO's recommend minimum of 4.45 health workers per 1,000 population.

Cadre	Number of workers	Ratio per 1,000 population
Doctors	334	0.20
Nurses (Including midwives)	1,342	0.80
Total	**1,676**	**1.00**

Table 14: Health workforce in Zanzibar (2020)[191]

6.2.2 Healthcare expenditure - Zanzibar

Government budgetary allocation to the health sector has seen a steady increase over the past four years increasing from USD 37 million in the FY 2017/18 to USD 51 million in FY 2020/21.[192]. However, when compared to the national budget, the health budget as a share of total government budget marginally declined from 7.7% in FY 2017/18 to of 7.4% in FY 2020/21.

[189] OCGS, Zanzibar statistical abstract 2020 - Pg.39
[190] OCGS, Zanzibar statistical abstract 2020 - Pg.41
[191] OCGS, Zanzibar statistical abstract 2020 - Pg.41
[192] UNICEF, Zanzibar Health Budget Brief 2019-2020

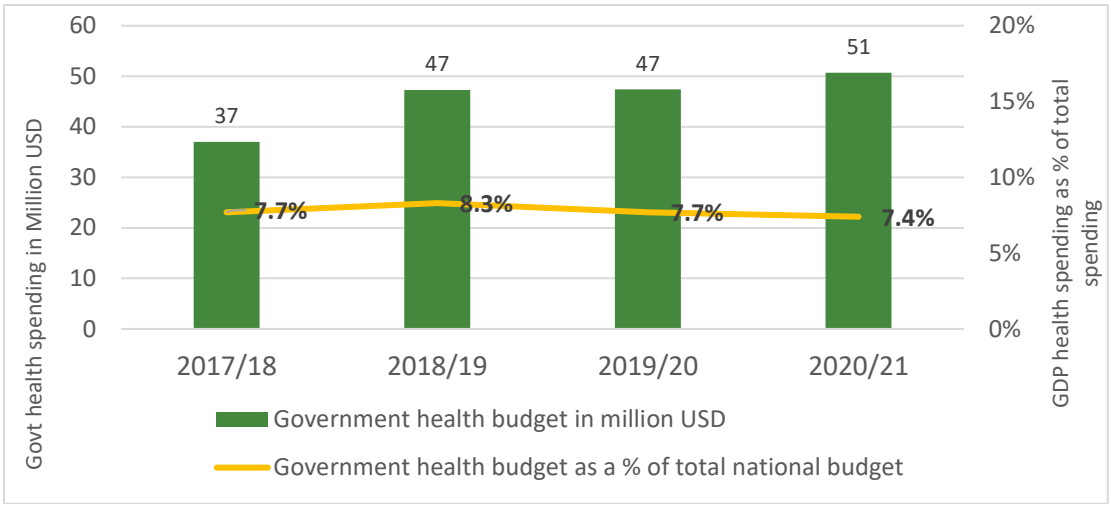


Figure 64: Zanzibar current healthcare expenditure (2017 - 2021, Per capita and as % of GDP) 18[193]

The vast majority of the healthcare budget goes towards funding core functions of the public healthcare system specifically wages for health workers, running costs of health facilities, and procurement of essential drugs and supplies. Residents of Zanzibar also enjoy Universal healthcare, which constitutes another significant government cost. Consequentially, only little is left for capital spending on medical and laboratory equipment.

[193] MOHSW, budget speech 2021/2022. UNICEF Zanzibar Budget brief 2019/2020

6.3. Medical and laboratory equipment landscape - Zanzibar

6.3.1. Medical and laboratory equipment value chain - Zanzibar

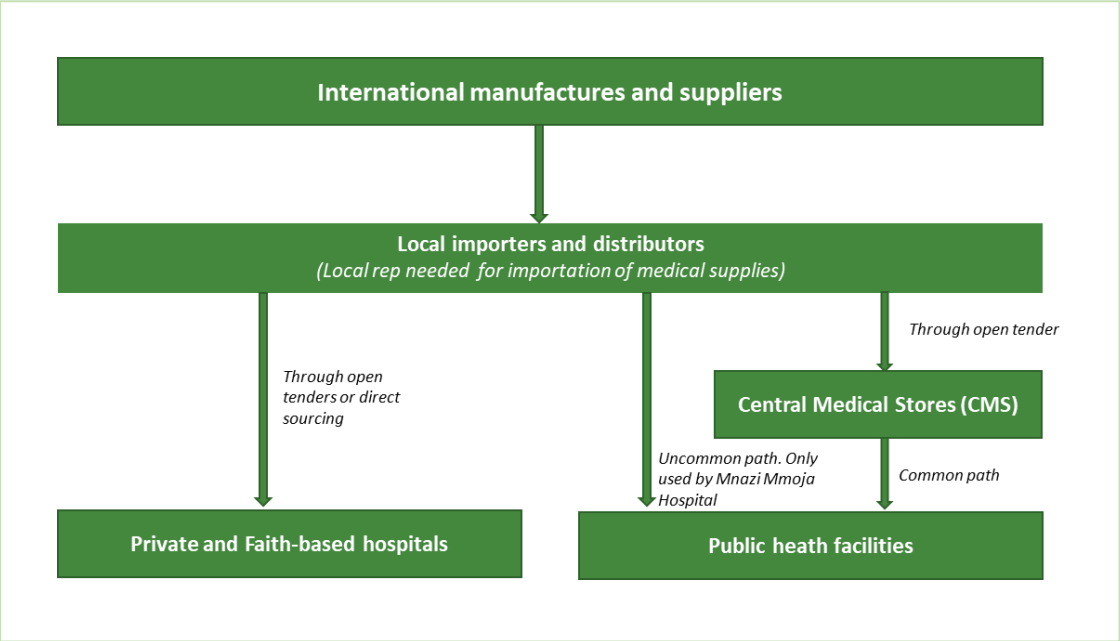


Figure 65: Zanzibar medical and laboratory equipment value chain (2021)[194]

Public sector

In Zanzibar, the Central Medical Stores (CMS), a department under the Ministry of Health and Social Welfare is responsible for procurement, storage and distribution of medical supplies and equipment to all public health facilities. CMS is able to procure supplies in bulk, which gives it leverage to negotiate for better pricing from suppliers. Public hospitals are obligated to get their supplies through CMS and only Mnazi Mmoja Hospital, Zanzibar's sole tertiary level facility, has the capability to procure independently and directly from suppliers.

Private sector

In the private sector, procurement of medical supplies is done directly from independent distributors and suppliers. In rare cases, private hospitals will also source from CMS where they stand to get better rates due to bulk purchasing.

6.3.2. Medical technology investment decision-making process - Zanzibar

Medical technology investment decisions in private hospitals are usually a participative process with multiple stakeholders involved including the product user, hospital administrators, accounting officers, procurement officers, and hospital management. The user, typically a lab manager or physicians, puts forward a request for equipment and provides clinical and business relevant information to justify the investment. The stakeholders will evaluate the purchase based on key metrics that include return on investment (ROI), immediate needs, hospitals technical capacity for the equipment, as well as the competitive edge such an equipment would provide against their competitors.

[194] africon research, 2021

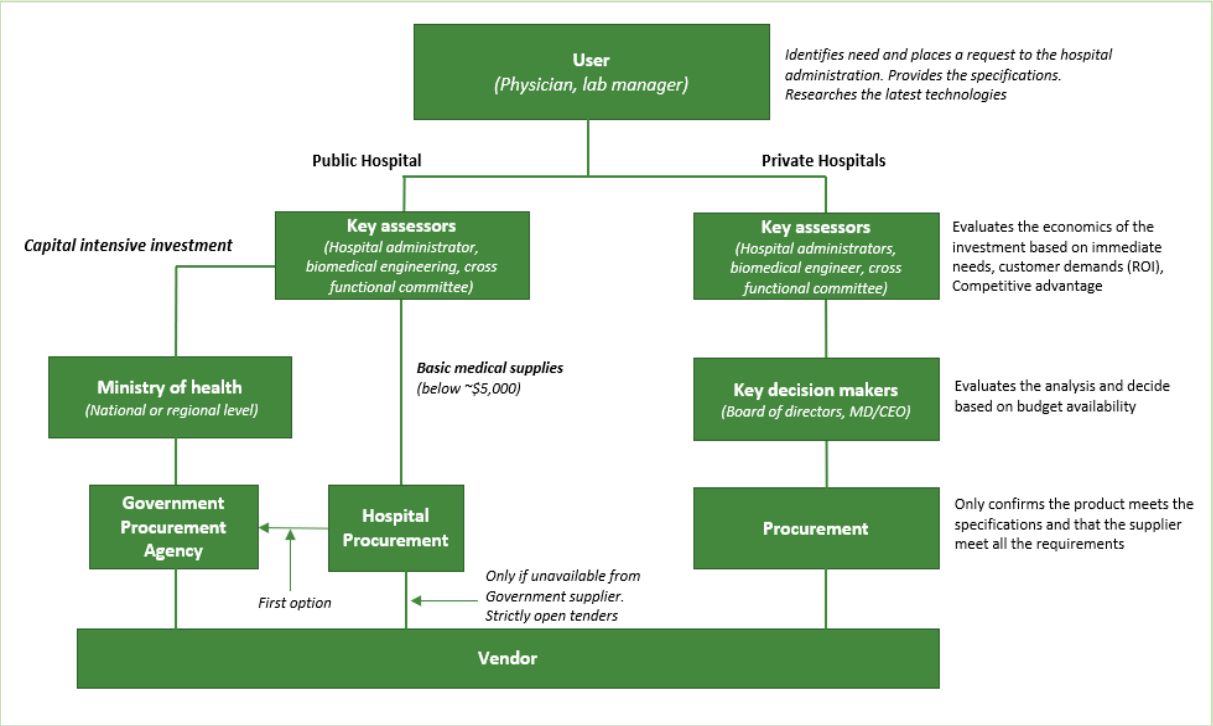


Figure 66: Medical and laboratory equipment investment decision-making process in Zanzibar (2021)[195]

Procurement in the public sector is however challenging due to bureaucracy and budget constraints. There are also multiple stakeholders and steps involved compared to the private sector. One major cause of delay is that almost all procurement has to be done through an open tender handled by the office of the Procurement Management Unit (PMU) under the Ministry of Health and Social Welfare (MOHSW). Another reason for delays is the number of stakeholders involved before a decision is made to procure the equipment in the first place. Within MOHSW, different stakeholders involved include the Drugs Management Unit (DMU), headed by the chief pharmacist who is responsible for all drug policies in Zanzibar, as well as the Chief Medical Officer. Budgetary constraints are an issue in addition to the governments' continued heavy depency on donors to fund core healthcare functions.

Source of information on new medical technology

According to research conducted by africon across the health sector in Zanzibar, the primary method healthcare practitioners learnt about new medical technology was via direct contact with vendors and online resources. Conferences and trade shows are unpopular due to cost and time involved especially since trade fairs are not held in Zanzibar, but in either mainland Tanzania or abroad.

Purchasing criteria

Zanzibar is highly price sensitive and therefore cost is often the primary factor considered during product selection. However, the product still has to meet technical specifications and the vendor has to meet the terms of service before being considered. Other factors, such as brand reputation, familiarity and maintenance cost are secondary considerations. Western brands are very popular and are considered higher quality, but China has made significant inroads in the recent years.

[195] africon research, 2021

6.3.3. Medical and laboratory equipment regulations - Zanzibar

Zanzibar Food and Drug Agency (ZFDA) is a semi-autonomous regulatory body under Ministry of Health Zanzibar (MOHSW). ZFDA was established under section 3 of the Zanzibar Food, Drug and Cosmetics Act 3/2017 and gave it the mandate of regulating safety, quality and efficiency of food, medicines, cosmetics, medical devices, and diagnostics equipment.

According to ZFDA, a medical device refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory which is:

a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
c) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

Import process

All medical devices to be imported into Zanzibar must be registered by the Zanzibar Food and Drug Agency (ZFDA). The applicant shall be a person who is resident in Zanzibar and must be licensed by ZFDA as medical device products dealer. If the applicant is not resident in Zanzibar, then he shall appoint a Local Responsible Person (Authorized representative) who must be residing in Zanzibar or company incorporated in Zanzibar and authorized by ZFDA to deal in medical devices products. Proof of official appointment shall be submitted to ZFDA. A cover letter, duly filled application form, referenced literature and two samples of the products need to be submitted to ZFDA. For devices with European certification (CE), the declaration of conformity from the manufacturer must be submitted, in addition to the EC certificate issued by the relevant body. Once an application has been accepted, the processing of application takes between 60 to 150 calendar days. The registration of a medical device is valid for five years unless suspended or revoked by ZFDA or terminated by the registrant.

Once registration is done, the importer can apply for an import permit. Importation can only be done by importers whose premises are dully registered by ZFDA. A registered importer applies for an import permit by filling an application form which should be accompanied by a proforma invoice. All importers are required to hold a valid importation permit issued by the Authority prior to shipping of the consignment.

Before shipping to Zanzibar, medical devices are subject to Pre-shipment Verification of Conformity (PVoC) and therefore must obtain the mandatory custom clearance documents and certificate of conformity (CoC). PVoC is carried out by authorized third-party agencies appointed by the Zanzibar Bureau of Standards (ZBS) who include SGS and Bureau Veritas.

On arrival at the ports of entry, medical devices will be inspected by a ZFDA Inspector to ensure that they comply with the approved specifications and regulations before they are released. Each consignment must be accompanied by an import permit, an original proforma invoice, a corresponding certificate of analysis for each batch and airway bill or bill of lading. Other government agencies may also conduct inspection activities as the rules and regulations apply. Such agencies may include Tanzania Revenue Authority (TRA), Zanzibar Revenue Board (ZRB) or other authorized agent. At the time of importation, medical products must have a valid shelf life not less than 60 % of the original shelf life.

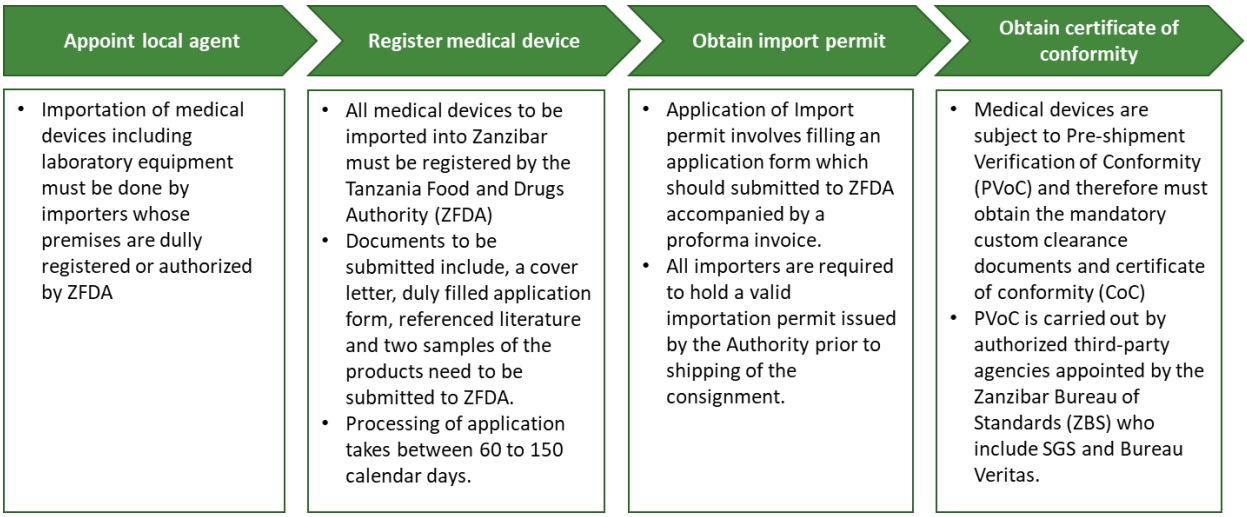


Figure 67: Zanzibar medical and laboratory equipment import process (2021)[196]

[196] africon research, 2021

6.3.4. E-health in Zanzibar

The state of E-health in Zanzibar

E-health is yet to gain wide adoption at a large scale in Zanzibar. The majority of hospitals still use manual record keeping and past patients' information is hard to extract for follow up purposes. Only a few private hospitals have adopted an e-health system with limited capabilities with the primary uses being patients record keeping and invoicing. Other benefits such as telemedicine, procurement and workforce management are yet to be leveraged fully.

E-health adoption challenges

The largest barrier to e-health adoption in Zanzibar is cost. Hardware requirements for e-health such as computers, servers and storage are an additional cost to the already over-stretched health budget. Zanzibar has also not adequately invested in the necessary infrastructure to support smooth e-health implementation such as reliable internet and stable power especially in rural areas.

E-health policies

The Government of Zanzibar has recognized digital health as an important enabler for health system strengthening. In an effort to accelerate e-health adoption, the government has drafted the Digital Health Strategy 2020/21-2024/25. Zanzibar seeks to leverage the power of e-health for data management, management of health commodities, human resource management, efficient disease surveillance and evidence-based health promotion. As an essential step towards laying a strong foundation for e-health, the Government has implemented several interventions including the countrywide installation of a fibre optic network, improving electrical power coverage as well as mobile networked coverage across Zanzibar.[197]

[197] MOH, Zanzibar Digital Health Strategy 2020/21-2024/25

6.3.5. E-learning in Zanzibar

Health training landscape

The State University of Zanzibar (SUZA) and Zanzibar School of Health (ZSH) are the primary health training institution on the island. They bear the responsibility of training health workers needed to keep Zanzibar's health system running smoothly. The training offered at these institutions are a mix of practical (50%) and theoretical in-class teaching (50%).

E-learning landscape and challenges

Both SUZA and ZSH have incorporated E-learning in their teaching, but in a limited scale. The wide adoption of e-learning in Zanzibar still has a long way to go due to several challenges including scarce electronic content, poor internet connectivity, limited access to computers and low digital literacy. Additionally, students and teachers prefer face to face learning. However, e-learning has been found to be very useful in making studies accessible to a larger number of students and the enable timely completion of syllabus in unforeseen circumstances like COVID-19.

I. Annex

Reagents market in East Africa

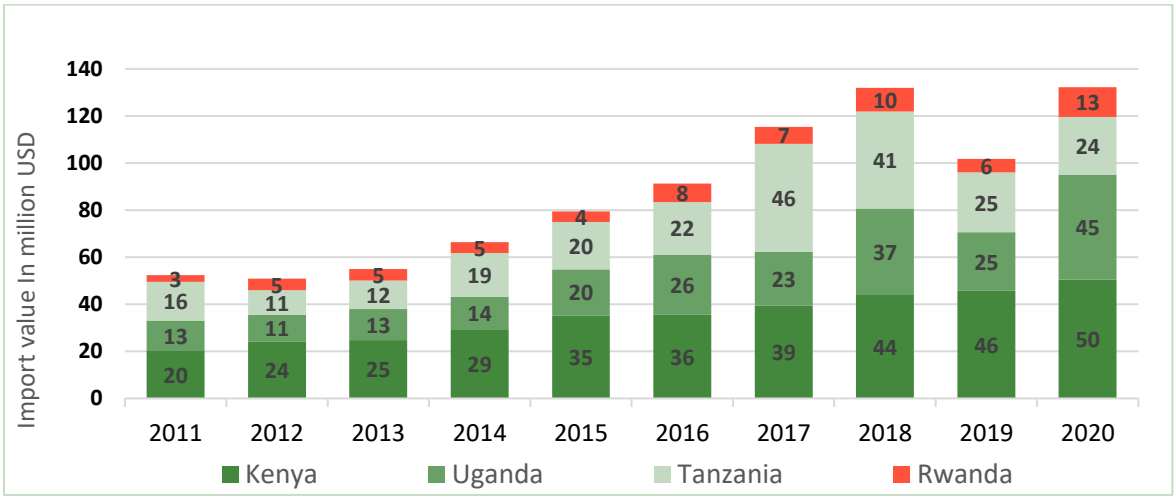


Figure 68: Import of reagents in East Africa (2011-2020, in million USD)[198]

Reagent imports have seen strong growth over the past decade, rising from USD 52 million in 2011 to USD 132 million in 2020 at a compounded annual growth rate (CAGR) of 10.8% annually. Rwanda has been the leading driver of this growth, recording a CAGR of 17.6% followed by Uganda (14.7%), Kenya (10.7%) and Tanzania (4.6%). Tanzania was the only country to record a decline of reagent imports from 2019 to 2020 which was mainly due to the Government's denial of Covid-19 and prematurely declaring victory over the pandemic.[199] Import of reagents is however expected to see a significant jump overall in 2021 as East African countries ramped up testing in the first half of the year. However, a decline is expected from 2022 going forward as more people are vaccinated and Covid-19 becomes less of a concern.

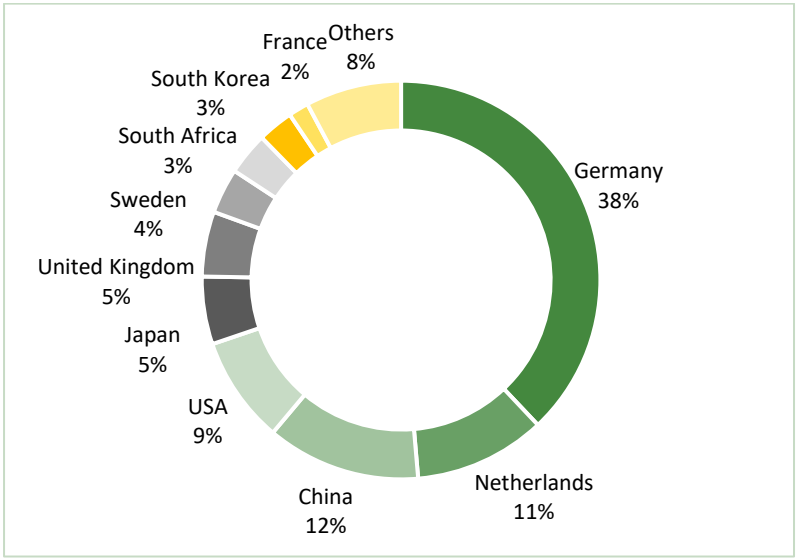


Figure 69: Import of reagents in East Africa by source (2020, in %)[200]

[198] UN comtrade
[199] BBC news 2020
[200] UN comtrade

Germany is the leading source of reagents in East Africa. This is mainly due to Germany also being the leading source of laboratory equipment accounting for 21% of all imports in 2020. In East Africa, majority of laboratory equipment is acquired through placement contracts whereby the manufacturer provides the machine for free, and the recipient is obligated to purchase a minimum volume of reagents from the manufacture at an agreed upon price.[201] As a result, the leading supplier of laboratory equipment is also going to also be the leading supplier of reagents. Germany is therefore expected to hold a lead in the reagent market for years to come.

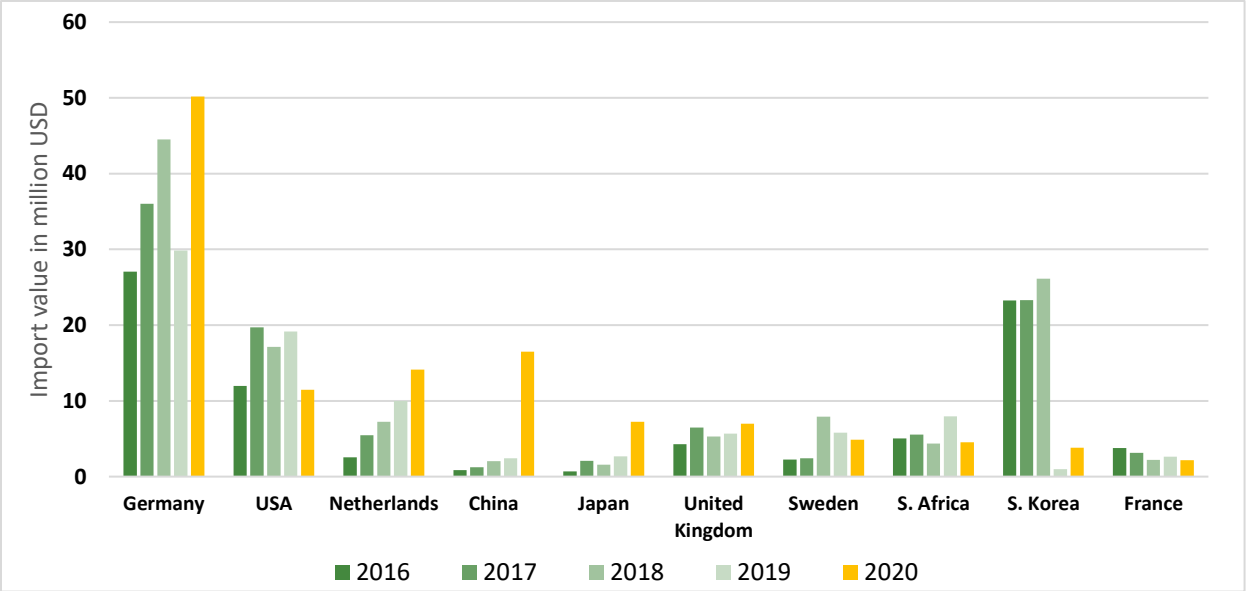


Figure 70: Import of reagents in East Africa by source (2016-2020, in million USD)[202]

Import of reagents from Germany has been on the rise over the past couple of years recording an all-time high of USD 50 million in 2020 driven primarily by the Covid-19 pandemic. However, China was the biggest gainer in 2020, recording a 587% increase from USD 2.4 million in 2019 to USD 16.5 million in 2020. Despite the spike in imports from China in 2020, this is not expected to continue after the Covid-19 pandemic. Germany and USA are expected to remain the leading sources of reagents due to the large concentration of machines from these countries and with users obligated to source their reagents from their suppliers.

[201] Ravishankar, Nirmala; Lehmann, Joel. 2015. Opportunities Abound: Public Private Partnerships for Laboratory Services in East Africa

[202] UN comtrade

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