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## BUSINESS INTELLIGENCE REPORT

# KENYA MARKET LANDSCAPE: SOLUTIONS TO STRENGTHEN COVID-19 VACCINES SUPPLY CHAIN

Client:

**PAHAL (Supported by USAID and implemented by IPE Global)**

**April 2022**

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# Abbreviations and Acronyms

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<b>AfCFTA</b>	African Continental Free Trade Area
<b>AU</b>	African Union
<b>COMESA</b>	Common Market for Eastern and Southern Africa
<b>ERP</b>	Enterprise resource planning
<b>FBO</b>	Faith based organization
<b>FDI</b>	Foreign Direct Investment
<b>HPTs</b>	Health Products and Technologies
<b>IFC</b>	International Finance Corporation
<b>KEBS</b>	Kenya Bureau of Standards
<b>KEMSA</b>	Kenya Medical Supplies Authority
<b>MEDS</b>	Mission for Essential Drugs and Supplies
<b>MOH</b>	Ministry of Health
<b>NGO</b>	Non-Governmental Organization
<b>PPB</b>	Pharmacy and Poisons Board
<b>PQS</b>	Prequalification Standard
<b>RPB</b>	Radiation Protection Board
<b>SEZ</b>	Special Economic Zone
<b>UHC</b>	Universal health coverage
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>WHO</b>	World Health Organization



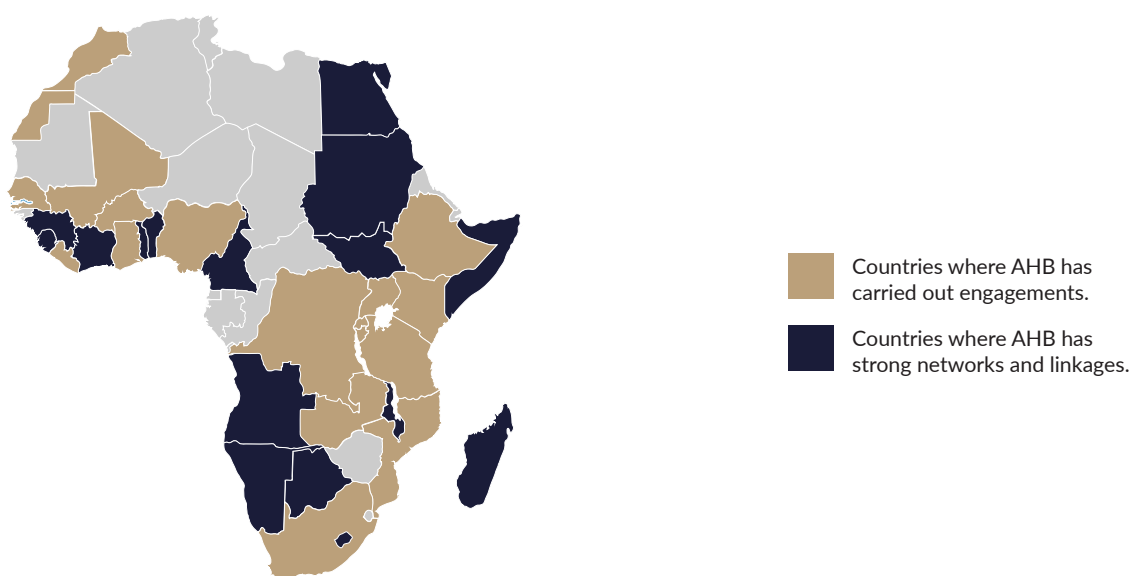
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# 1. Background

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## 1.1 Africa Health Business

This report is prepared by Africa Health Business (AHB), a boutique consulting and advisory firm that aims to improve access to equitable healthcare in Africa. Through a private sector lens, AHB provides organisations with actionable insights to grow their health agenda in Africa. We advise some of the largest and globally recognised institutions, companies, as well as investors on the African continent, helping them to understand complex market dynamics and manage challenging relationships with demanding and critical stakeholders.



*Figure 1: Countries where AHB is active*

## 1.2 IPE Global Limited and Partnerships for Affordable Healthcare Access and Longevity (PAHAL)

**IPE Global Limited** is an international development consulting group, headquartered in India, known for providing technical assistance and solutions for development and sustainable growth in developing countries. IPE Group has partnered with Sustainable Access to Markets and Resources for Innovative Delivery of Healthcare (**SAMRIDH**), a financing initiative funded by USAID that supports high impact and commercially sustainable solutions targeted at improving healthcare services for vulnerable communities. SAMRIDH supports innovators and entrepreneurs through their critical stages of growth, maximizing their efforts towards building an inclusive healthcare system.

**PAHAL** is a flagship ‘innovations in financing’ platform supported by USAID and managed by IPE Global. The project focuses on innovative financial models that enable governments and donors to supplement traditional financing with new forms of conditional and catalytic support; and private investments and other non-donor sources of funding for generating social impact. The program promotes health financing models that align new pools of capital and provide catalytic support to proven innovations for improved access to quality, affordable healthcare solutions for poor and vulnerable populations.

The COVID-19 pandemic has caused a strain on the supply chain of health commodities globally, particularly those requiring cold chain storage and transportation. IPE global, through PAHAL are supporting the following organizations to provide solutions to the challenges posed by COVID-19, with the aim of strengthening Africa's health supply chain in order to deliver COVID 19 vaccines equitably across the continent.

**Blackfrog Technologies** is a biotechnology organization that has developed EMVÓLIO - a patented rapid cooling technology for safe last-mile transport of vaccines, breast milk, blood, serums, medications and specimens with minimal freeze-thaw cycles. EMVÓLIO has been designed to be carried in a backpack and has been developed in accordance with WHO PQS E003 specifications.

**PLUSS Advanced Technologies** is a company which deals in materials research and manufacturing in the field of Specialty Polymeric Additives for enhancing polymer properties and Phase Change Materials (PCMs) which are essential for thermal energy storage. The organization has products with the capacity to hold temperatures at different points critical in storage of health specimens.

**AWL** is a tech-based logistics and supply chain management company providing smart logistics solutions driven by cutting edge technology. The organization provides temperature-controlled logistics solutions for the healthcare and pharmaceutical industry.

AHB has been contracted by IPE Global under the PAHAL initiative, to provide advisory services and market insights to the above-mentioned organizations, for the Kenyan market.

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## 2. Economic Landscape

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### 2.1 Africa

Home to approximately 1.3 billion people spread across 54 countries, Africa is the second largest continent in the world covering a total land area of about 30.3million square kilometres.

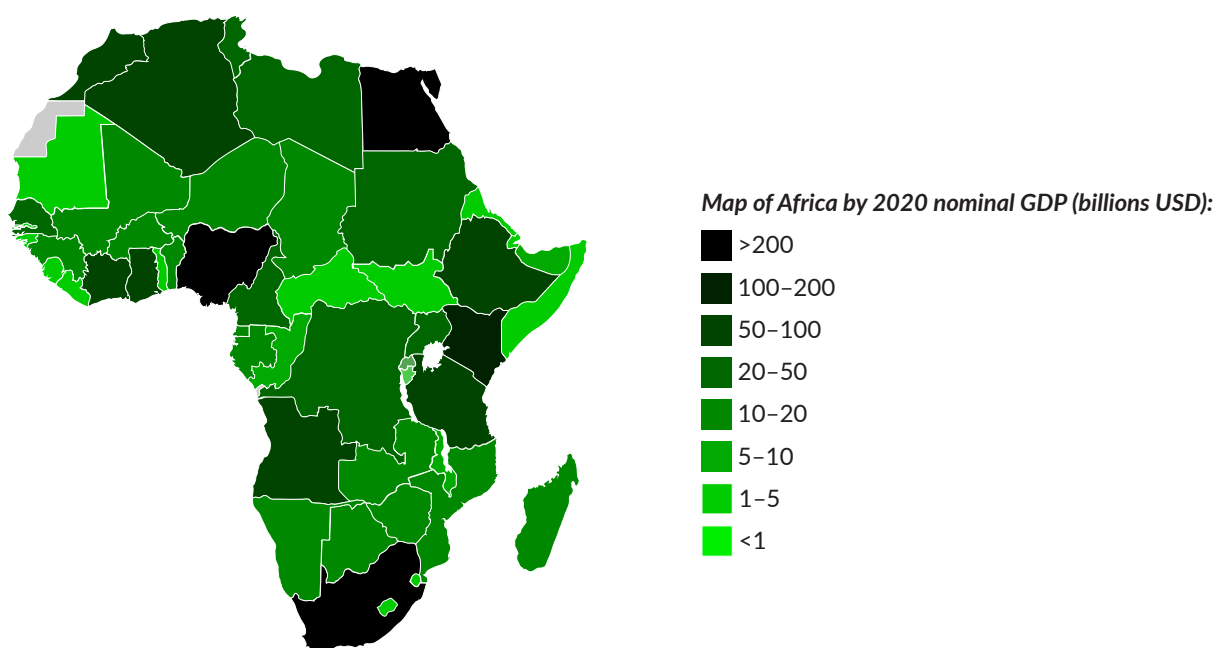
Most of Africa's economy, except for South Africa and Northern Africa, can be described as underdeveloped. Evidently, the continent is rich in natural resources, but has over the years remained predominantly agricultural with subsistence farming being the main source of living for more than 60% of the population. Trade, industry and agriculture have been on the rise but compete with a rapidly expanding population.

The table below shows some of the most important economic statistics in Africa:<sup>[1]</sup>

**Table 1: Selected economic indicators Africa 2020**

GDP	\$2.7 trillion (nominal), \$6.7 trillion (PPP)
GDP growth	3.7%
GDP per capita	\$1,970
Unemployment	15%
Life expectancy	61

Economic growth was predicted to contract by 3.3% in 2020 due to the COVID-19 pandemic, but contracted by only 2.0% due to lower than expected COVID-19 related morbidity and mortality and a quick recovery in commodity prices.<sup>[2]</sup> Growth in 2021 is now estimated to have risen between 2.3 and 3.4% with some countries like Kenya estimated to have grown by 5%.<sup>[3], [4]</sup> The 2022 growth outlook for Sub-Saharan Africa is promising, predicted at 3.8% depending on extension of COVID-19 vaccine reach. A World Bank report in October 2021 illustrated this interdependence, indicating that “Faster vaccine deployment would accelerate the region’s growth to 5.1 percent in 2022 and 5.4 percent in 2023”. The report further cautions that if vaccine coverage continues to lag, the predicted growth could be dramatically lower possibly going as low as 2.4% in 2023 due to the consequent need for ongoing containment measures that will invariably decrease spending.<sup>[5], [6]</sup>



**Figure 2: Map of Africa by 2020 nominal GDP (billions USD)**

**The African Union (AU)** is the representative continental body for 55 African member states that focuses on increasing cooperation and integration of African states to drive Africa’s growth and economic development.

Several continental frameworks have been developed to address the development goals in Africa. One such framework is the **African Continental Free Trade Area (AfCFTA)** that aims at accelerating intra-African trade and boosting Africa’s trading position in the global market by strengthening Africa’s common voice and policy space in global trade negotiations. As at 5 February 2021, **36 countries** have ratified the AfCFTA agreement.

A growing focus on regional integration has led to the establishment of special economic zones, which are yet another framework to aid in economic diversification across Africa. Most of the 237 SEZs on the continent are located in East Africa, with Kenya having 61.<sup>[7]</sup>





Figure 3: No. of SEZs by country [7]

The African pharmaceutical market is worth USD 13.6 billion. [8] With the health supply chain challenges experienced due to the COVID-19 pandemic, African countries have become more aware of the need for self-reliance in manufacture of health products and technologies. In September 2021, IFC and the Rwanda Development Board signed a collaboration agreement to develop vaccine manufacturing capacity in the Kigali SEZ and contribute to expanding vaccine production in Africa. [9] Further, six African nations have been selected for mRNA vaccine production by WHO. The 6 countries: Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia, shall receive technical support on how to produce mRNA vaccines from the global mRNA technology transfer hub in Cape Town, South Africa. [10]

UNCTAD reports that despite the proliferation of SEZs on the continent, the disproportionate focus on fiscal incentives without improving other key drivers of a country's comparative advantage has made their impact on economic growth slower than anticipated. [7]

## Healthcare expenditure and disease trends

Health expenditure as a percent of GDP in sub-Saharan Africa in 2019 was 4.925 compared to 9.845 globally. Lesotho had the highest proportion of expenditure in sub-Saharan Africa at 11.27% with Republic of Congo having the least expenditure at 2.08%. [11]

Whilst non communicable diseases such as cancer, cardiovascular diseases and diabetes are increasingly becoming the main cause of mortality in sub-Saharan Africa, where the diseases were responsible for 37% of deaths in 2019 [12]. HIV, Malaria and TB are still of concern, accounting for more than 1.2 million deaths per year on the African continent. Added to this, there is a growing threat of emerging and re-emerging infectious diseases, most of which are vaccine preventable. [13] As seen with the COVID-19 pandemic, epidemics that require mass vaccination of populations are sure to put a strain on existing routine immunization resources. One of the ways we can increase the resilience of Africa's health systems in the wake of these emerging and re-emerging health threats is to strengthen the vaccines supply chain, including strengthening of the infrastructure needed to distribute vaccines from source to the last mile.

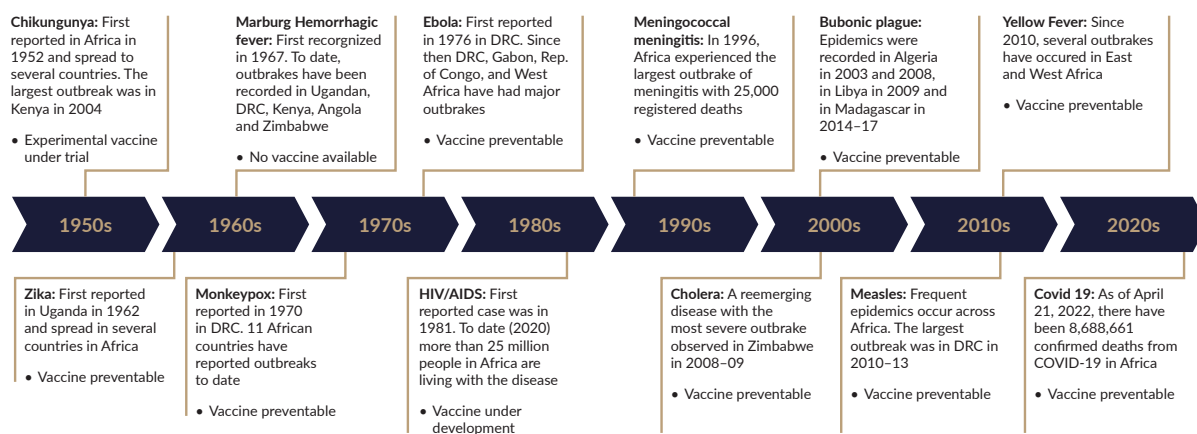


Figure 4: Timeline of major emerging and re-emerging diseases in Africa, 1950-2020

## 2.2 East Africa

East Africa (EA) is the eastern sub-region of the African continent comprising seven countries namely Kenya, Uganda, Tanzania, Rwanda, South Sudan, Burundi and the Democratic Republic of Congo. The EA region is home to about 177 million people with 22% of its population living in urban areas. The region covers a land area of about 2.5 million square kilometres. <sup>[14]</sup> The representative body of East African States is the East African Community (EAC), a regional intergovernmental organisation of the seven Partner States with its headquarters in Arusha, Tanzania.

In 2019, East Africa recorded the highest economic growth rate of 5% in the continent. Projected GDP growth in East Africa before COVID-19 was forecasted to be above 5%. The economic growth in East Africa is positively contributing to the development in Africa overall.

The East African Foreign Direct Investment (FDI) inflow also increased from \$5.7 billion to \$11.5 billion within one year in 2019. During this period, inflows from all countries in East Africa increased significantly. The high increase was largely attributed to China which is the East Africa's largest investor. Chinese investment accounts for almost 60% of FDI inflow in East Africa. A significant percentage of current investment initiatives are going into the space technology, manufacturing, and service sectors. FDI inflows created 89,877 jobs in 2018 and 211,084 in 2019. Employment increased in Uganda, Tanzania, Rwanda, Kenya, Burundi, and South Sudan. <sup>[15]</sup>

The table below shows a snapshot of some significant statistics of the EA economy: <sup>[16]</sup>

Table 2: Selected economic indicators East Africa 2020

GDP	\$193 billion
GDP growth	5%
GDP per capita	\$2,700
Unemployment	9.24%
Life expectancy	66

## 2.3 Kenya

The Republic of Kenya is in East Africa covering an area of about 580,367 square kilometers. Kenya has a population of about 53 million people with 28% residing in urban areas of the country. <sup>[17]</sup> Kenya's Vision 2030 is the current blueprint for the growth of its economy with three pillars namely economic, social, and political. The economic pillar seeks to achieve consistent economic growth at an average 10% for 23 years since its inception in 2007. The Kenya Vision 2030 aims to realise a 10 per cent GDP growth and significantly reduce the number of people living in extreme poverty.

The Kenyan economy is a market-based economy with a few state enterprises. The top performing industries in Kenya include agriculture, forestry, fishing, mining, manufacturing, energy, tourism, and financial services. Prior to the COVID-19 pandemic, Kenya had the highest rate of economic growth in Africa, with an annual average growth rate of 5.9% between the years 2010 and 2018. In 2020, it was reported that Kenya was the third largest economy in Sub-Saharan Africa after Nigeria and South Africa. <sup>[18]</sup> In addition, Kenya was ranked 56th out of 190 countries in the World Bank ease of doing business rating, which is an improvement from a ranking of 61st in 2019. Generally, the government of Kenya is open to investments as it has put in place requisite regulatory reforms to simplify both foreign and local investments. <sup>[19]</sup>

The national accounts data indicate that the Kenyan economy contracted by 0.3% in the year 2020 compared to reported growth of 5.0 percent in 2019. The fall in economic growth was attributed to the adverse effects of the COVID-19 pandemic which disrupted economic activities especially in the service industry. <sup>[20]</sup> In 2014, Kenya became a Lower Middle-Income Country (LMIC) by the World Bank standards owing to its current Gross Domestic Product (GDP) of approximately USD 101.01 billion. Currently, Kenya serves as the major entry point to the East African market which has a population of about 300 million people. <sup>[21]</sup> Although the economy was adversely affected by the COVID-19 pandemic, it is projected to grow by 5.9% by the end of 2022. <sup>[22]</sup>

The aggregate demand in Kenya is significantly driven by the rate of household consumption, which declined in 2020 due to restriction measures and loss of livelihoods owing to COVID-19.

The table below shows a snapshot of the current economic indicators in Kenya as of 2020. <sup>[23]</sup>

**Table 3: Selected economic indicators Kenya 2020**

GDP	\$101.01 billion
GDP growth	-3.2%
GDP per capita	\$1,878.58
Unemployment	6.6%
Life expectancy	66

To attain inclusive and sustainable growth of the economy, Kenya has demonstrated an open and welcoming stance to partnerships between the public and non-state sectors. The Kenya Private Sector Alliance (KEPSA) spearheads public private dialogue (PPD) with government through four main stakeholder platforms which include the Presidential roundtable, the Ministerial Stakeholder Forums, the House Speakers' Roundtables, and the Council of Governors Forum. <sup>[24]</sup>

# 3 Kenya's Health System

## 3.1 Overview

Kenya Vision 2030 launched in 2006 seeks to improve the health and well-being of Kenyans. The Kenya Constitution 2010 entrenched a rights-based approach to health and changed how healthcare is delivered, devolving the bulk of health service provision to the 47 counties. The national government, through the Ministry of Health (MOH) is still responsible for financing and policy development, including the management of national referral hospitals, and monitoring quality standards through national health agencies. [25]

Guided by the Kenya Health Policy 2014–2030, Vision 2030, the Constitution of Kenya 2010 and the President's Big 4 Agenda, the Kenya Health Sector Strategic Plan (KHSSP) 2018 was developed and is currently being implemented. The figure below illustrates the conceptual framework of the KHSSP 2018 in the context of UHC. [26]

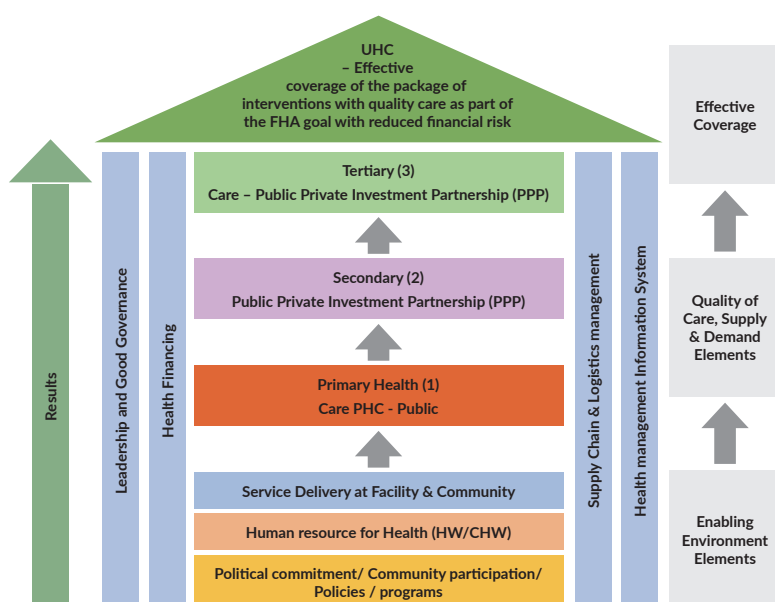
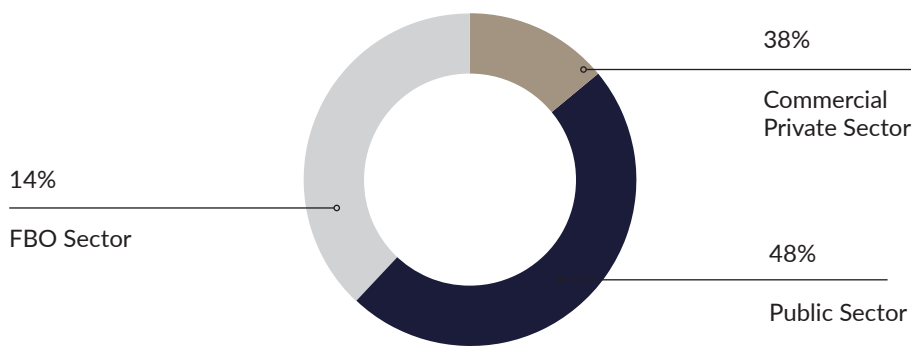


Figure 5: The conceptual framework of the KHSSP 2018 in the context of UHC

## 3.2 Service provision, regulation and governance

Health service provision is shared between the public sector, faith-based organizations and the private sector. The public sector is the largest and includes all government health facilities (hospitals, clinics and dispensaries), medical schools and the public pharmaceutical supplies aggregator KEMSA. The non-commercial private sector includes Faith Based Organizations (FBOs) and Non- Governmental Organisations (NGOs), which include mission health facilities (hospitals, clinics and dispensaries), medical schools and Mission for Essential Drugs and Supplies (MEDS) which procures and distributes medical supplies to this subsector. The private commercial (“for-profit”) sector includes healthcare facilities, medical distributors/suppliers, pharmaceutical/medical manufacturers, payers, health ICT providers, health management advisory and training institutions. The figure below indicates the ownership of registered health facilities in Kenya.

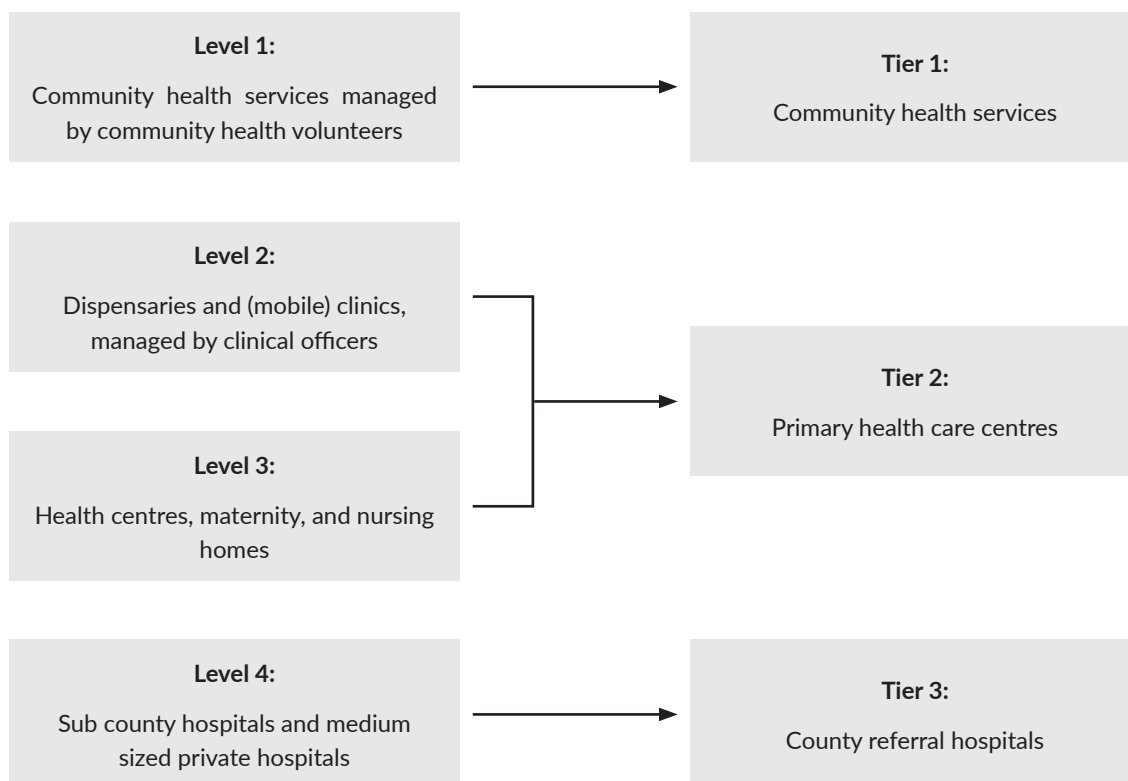


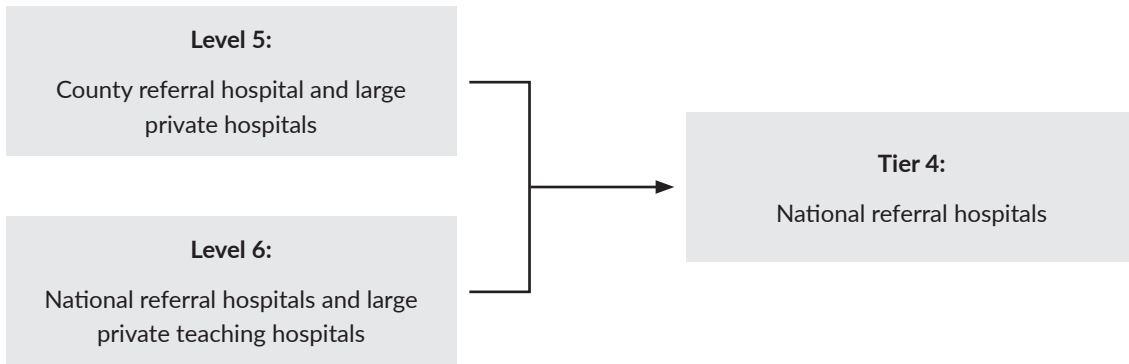
**Figure 6: Ownership of health facilities in Kenya**

The public health system is organized into six levels I to VI comprising community health services, dispensaries, health centres, subcounty hospitals, county referral hospitals and national level referral hospitals respectively.

All healthcare facilities must be licensed and registered by the Kenya Medical Practitioners and Dentists Council (KPMDC), with Pharmacies and Laboratories within or without the healthcare facilities requiring to be registered by the Pharmacy and Poisons Board (PPB) and the Kenya Medical Laboratory Technologists and Technicians Board (KMLTTB). The National Ministry of Health (MOH) maintains the Kenya Master Facility List (KMFL) that includes all recognized healthcare facilities in Kenya.

The National Ministry of Health is headed by the Cabinet Secretary for Health who is responsible for overall management, technical direction, and coordination of the ministry’s activities. The Cabinet Secretary is assisted by the Principal Secretary, responsible for financial and personnel administration and audit of the ministry and its agencies. The Director General of Health serves as the technical lead in the ministry while the Chief Administrative Secretaries deputize the Cabinet Secretary.



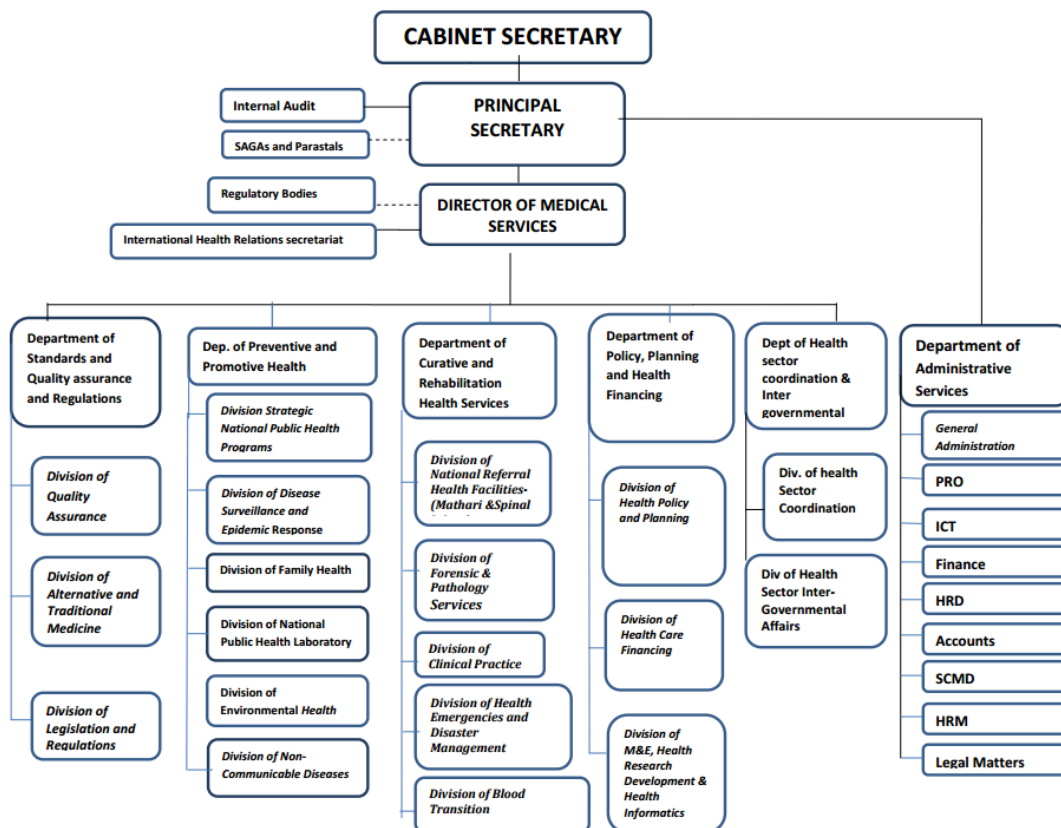


**Figure 7: Health service provision framework**

The figure below shows the organizational structure at the Ministry of Health. A reorganization of the structure has been ongoing (not yet operationalized) since the Health Act of 2017 provided for a Director General of Health with various technical Directorates reporting to him/her.

The semi-autonomous agencies that are under the Ministry of Health are Kenya Medical Supplies Authority (KEMSA), Kenya Medical Research Institute (KEMRI), National Hospital Insurance Fund (NHIF), Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenyatta University Teaching Research and Referral Hospital (KUTTRH), Kenya Medical Training College (KMTC), National AIDS Control Council (NACC), the HIV/AIDS Tribunal and the National Quality Control Laboratory.

The training and practice of healthcare professionals is regulated by their respective health professional councils, whilst health products and technologies are regulated by the PPB and the Radiation Protection Board (RPB).



**Figure 8: Ministry of Health, Kenya organizational structure**

The MOH works closely with other government ministries, recognizing that health is enabled by a wider environment and ecosystem that is dependent on all sectors. The table below shows the respective supportive and enabling roles of non-health government Ministries to the health of Kenyans.

**Table 4: Supportive and enabling roles of non-health government Ministries to the health of Kenyans**

Ministry, Department, Agency	Role in Health
Ministry of Planning and Devolution	<ul style="list-style-type: none"> <li>Promote sustainable population growth.</li> <li>Ensure youth and gender is mainstreamed in all sector policies.</li> <li>Provide data that is required to inform health (promotion) planning (e.g. KDHS, vital statistics).</li> <li>Create enabling environment for the implementation of the MTP towards achievement of health goals under vision 2030.</li> <li>Support implementation of transition implementation plans to facilitate devolution of the health system.</li> </ul>
Ministry of Agriculture, Livestock and Fisheries	<ul style="list-style-type: none"> <li>Incorporate considerations of health in safe food production systems, manufacturing, marketing and distribution.</li> <li>Ensure food security for the whole population.</li> </ul>
Ministry of Lands, Housing and Urban Development	<ul style="list-style-type: none"> <li>Promote urban and housing designs and infrastructure planning that take into account Urban Development health and wellbeing of the population's urbanisation.</li> <li>Strengthen access to land, and other culturally important resources, in particular for women.</li> </ul>
Ministry of Transport and Infrastructure	<ul style="list-style-type: none"> <li>Ensure optimal planning of construction and maintenance of roads, bridges with due consideration for location of health services in order to facilitate physical access to health services e.g. express lanes for ambulances.</li> <li>Ensure availability of infrastructure to incentivise and support physical activity (cyclists, pedestrians).</li> <li>Facilitate data and voice communication within health sector and with other sectors.</li> </ul>
Ministry of Industrialisation and Enterprise	<ul style="list-style-type: none"> <li>Ensure work and stable employment and entrepreneur opportunities for all people across different socio economic groups.</li> </ul>
Ministry of Education, Science and Technology	<ul style="list-style-type: none"> <li>Support education of men and women in order to enable them to increase control over the determinants of health and thereby improve their health.</li> </ul>
Directorate of Public Prosecution Ministry of Interior and National Coordination Attorney General	<ul style="list-style-type: none"> <li>Have fair justice systems, particularly in managing access to food, water &amp; sanitation, housing, work opportunities and other determinants of wellbeing.</li> <li>Ensure security (a major determinant of access to health).</li> <li>Ensure coordination of optimal disaster management (mitigation and response).</li> </ul>

Ministry, Department, Agency	Role in Health
Immigration	<ul style="list-style-type: none"> <li>• Ensure wellbeing of refugee populations.</li> <li>• Ensure all visitors comply with regulation with respect to required vaccinations and sharing of critical information concerning their health status under special circumstances e.g bird flu</li> </ul>
Ministry of Labour, Social Security and Services	<ul style="list-style-type: none"> <li>• Promote progressive workplace and safety policies that safeguard the health of workers.</li> <li>• Develop social policies for protection of vulnerable groups.</li> <li>• Ensure development and enforcement of proper regulation of cultural practitioners.</li> </ul>
Ministry of Sports, Culture and Arts	<ul style="list-style-type: none"> <li>• Promote sport and physical exercise.</li> </ul>
Ministry of Environment, Water and Natural Resources	<ul style="list-style-type: none"> <li>• Influence population consumption patterns of natural resources to meet the health needs of current generations without compromising the ability of future generations to meet their own health needs.</li> <li>• Develop and implement legislation to control/minimise pollution.</li> <li>• Promote access to safe and clean water to the population</li> </ul>
Ministry of commerce tourism and East African affairs	<ul style="list-style-type: none"> <li>• Development and harmonisation of health policies and regulations.</li> <li>• Coordination of common health sector activities.</li> <li>• Regional centres on health.</li> <li>• One border stop on health matters.</li> </ul>

At the county level, health affairs are managed by a member of the County Executive Committee (CEC) who is appointed by the governor. The Chief Officer for health is responsible for financial and personnel administration and audit, whilst the Director for Health is the technical lead for health matters, overseeing the County Health Management Team.

To attain inclusive and sustainable growth of the economy, Kenya has demonstrated an open and welcoming stance to partnerships between the public and non-state sectors. The Kenya Private Sector Alliance (KEPSA) spearheads public private dialogue (PPD) with government through four main stakeholder platforms which include the Presidential roundtable, the Ministerial Stakeholder Forums, the House Speakers' Roundtables, and the Council of Governors Forum. <sup>[24]</sup>

### 3.3 Financing

The Kenyan health system is funded by government revenues, National Health Insurance Fund (NHIF) contributions, private health plans and donations / external funding. In 2018, the total health expenditure (THE) as a percentage of GDP stood at 5.2%. The private sector contributed the largest share at 42.4%, followed by the government at 42.1%. In the same year, out-of-pocket (OOP) expenditure as a percentage of THE was 23.6%. <sup>[27]</sup>

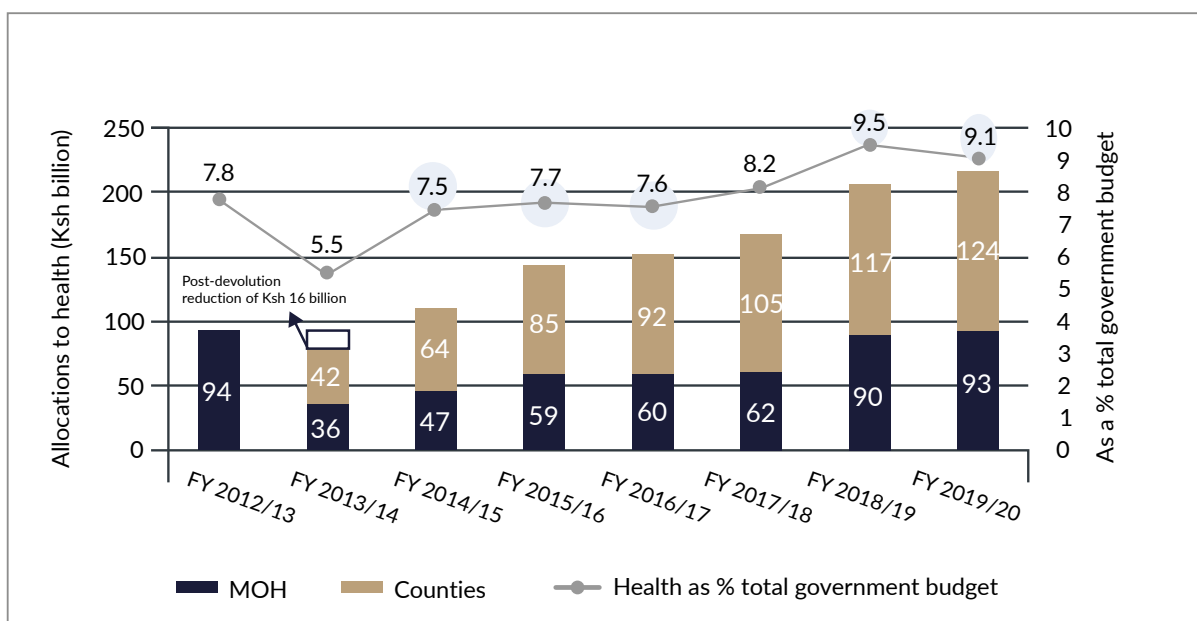


**Table 5: Selected statistics in healthcare in Kenya in 2018**

Indicator	Value
Current health expenditure (% of GDP)	5.17
Current health expenditure per capita (USD)	88.39
Out-of-pocket expenditure (% current health expenditure)	23.62
External health expenditure per capita (USD)	27.79

In the financial year 2021/2022, the Government of Kenya allocated KES 121.1 billion for the health sector. About KES 8.7 billion was allocated for Kenya COVID-19 Emergency Response Project, KES 3.9 billion for vaccines and enhancement of immunization programs, and KES 14.3 billion for purchase of COVID-19 vaccines and related expenditures in FY 2021/22. <sup>[28]</sup>

Although Kenya’s budget allocation to health increased after devolution, there are still challenges in addressing the health needs of the population. Kenya is yet to meet the target pledge of 15 percent of the total budget to health as it was articulated during the Abuja Declaration in 2001. The figure below shows the allocation of health funds in county and national governments.



**Figure 9: Allocation of health funds in county and national governments 2013-2020** <sup>[29]</sup>

Despite the constitutional mandate guaranteeing the right to health, and the various policy imperatives penned to ensure affordable and quality healthcare for all Kenyans, health still lags other sectors in government funds allocation. The figure below shows the comparative allocation of government funds across various sectors between 2017 and 2020.

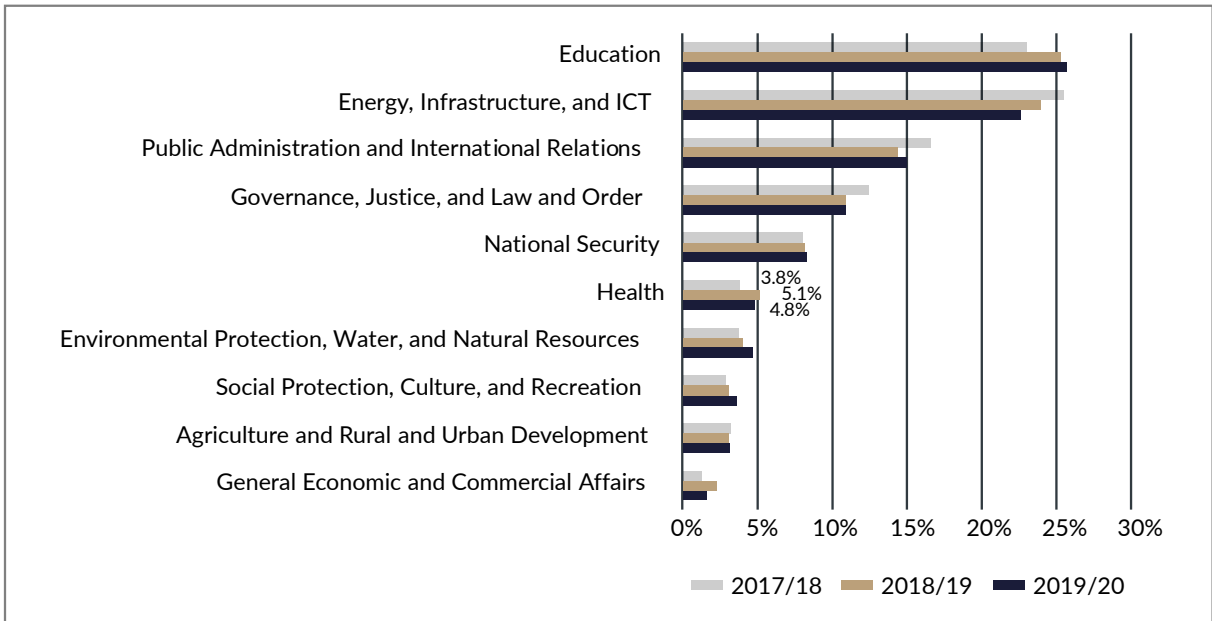


Figure 10: Kenya budget allocation per sector 2017 to 2020 [29]

### 3.4 Health Products and Technologies (HPTs) Supply Chain

Local pharmaceutical production accounts for 30% of the USD 1 billion Kenyan pharmaceutical market. Foreign multinationals enjoy the largest share by value of this market. Domestic consumption accounts for less than 50% of locally produced medicines, with USD 63 million worth of products exported by Kenya to the COMESA region. [8]

Kenya is currently the largest producer of pharmaceutical products in the COMESA and EAC region. The value chain of local pharmaceutical product currently comprises of: Production of finished pharmaceutical products; packaging and branding and, marketing and distribution. The portfolio of products comprises of generic products and includes creams, ointments, syrups, tablets, capsules and sterile products including both small volume parenteral (SVP) and high volume parenteral (LVP) fluids. Kenya was the second African country after South Africa to produce generic antiretroviral drugs in the continent.

Despite advancement in the quality of local pharmaceutical manufacturing in recent years catalysed by the UNIDO led GMP roadmap initiative, [30] Kenya still does not have capacity to produce vaccines and other biologic products. The challenges faced by the country in accessing COVID-19 vaccines have however led to firm government action to introduce local production of human vaccines, with the recently launched Kenya Biovax Institute set to start local packaging of vaccines in a fill and finish facility in 2022, and full production of vaccines in 2024. [31]

#### Public sector

The public sector is obligated by law to source HPTs through the government medical procurement entity KEMSA whose procurement process is largely through open national and international tenders and is guided by the public procurement Act. [32] The procured HPTs are determined by the demand of the counties and encompass the essential medicines list. [33] It is only when products are unavailable at KEMSA can public health facilities or counties procure from private sources. [34] KEMSA no longer receives direct funding from the GOK, as it relies on a revolving fund which is dependent on the payment from the public purchases as well as programmatic support from multilateral donor agencies such as UNICEF, Global Fund, USAID, KFW, UNFP, WHO and others. KEMSA's business processes are fully automated through an enterprise resource planning (ERP) system.

## Experiences with KEMSA

- KEMSA procures medical supplies and equipment for which a lot of competition exists. It is mentioned that KEMSA is extremely price sensitive.
- KEMSA often requires a 3-year track record of supplying in Kenya, including suppliers and recipient hospital audit information that is verified through (local) lawyers.
- Public sector often has payment terms of 120 days or more, paying at the last day or sometimes delayed.
- Suppliers need to engage with KEMSA to introduce their products and solutions and demonstrate to the officials how they can improve the health space as well as show their competitive advantage. For the process to be faster, there should be good will between the suppliers and the GOK.

## Private not-for-profit sector

The Faith Based Organization (FBO) and Non-Governmental Organizations (NGO) sector in health comprises several organizations such as the Christian Health Association of Kenya (CHAK), Kenya Conference of Catholic Bishops (KCCB), Supreme Council of Kenyan Muslims (SUPKEM) and the Kenya Red Cross and Health NGOs Network Kenya (HENNET). In most cases, FBOs are involved in primary healthcare provision with only a small number offering specialised services, for example AIC Kijabe Hospital which is classified as a referral hospital. FBOs and NGOs in health are said to comprise the private non-for-profit health subsector.

The NGOs and FBOs source their HPTs through the Mission for Essential Drugs and Supplies (MEDS) and supplies are based on a centralized formulary. MEDS is a Christian non-profit organization registered as a Trust of the Kenya Conference of Catholic Bishops (KCCB) and Christian Health Association of Kenya (CHAK). The organisation has a WHO prequalified quality control laboratory and has three main functions which include health advisory services, supply chain and distribution, and quality assurance services.

## Commercial Private Sector

The private for-profit sector comprises manufacturers, distributors, wholesalers and healthcare providers. Procurement of HPTs is done from both overseas and local suppliers whether these suppliers be manufacturers or their authorized distributors. The products procured are purely based on market demand. The processes of regulatory affairs, marketing, sale and distribution are carried out either by the pharmaceutical manufacturer, the original equipment manufacturer (OEM) or the authorized distributor as per the terms of the legal agreements.

The figure below shows the overview of procurement processes across the public, private, and NGO/FBO health sectors

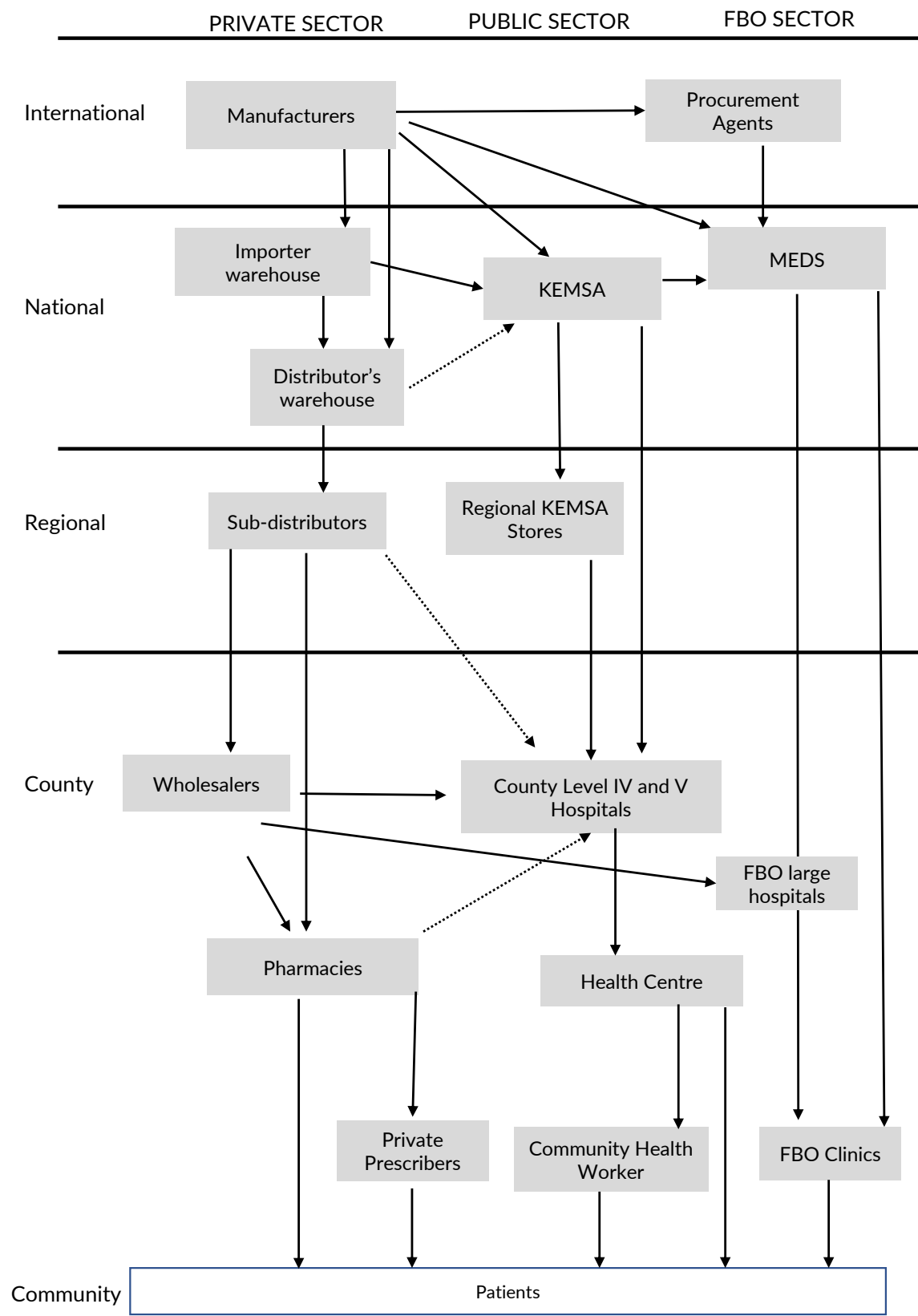
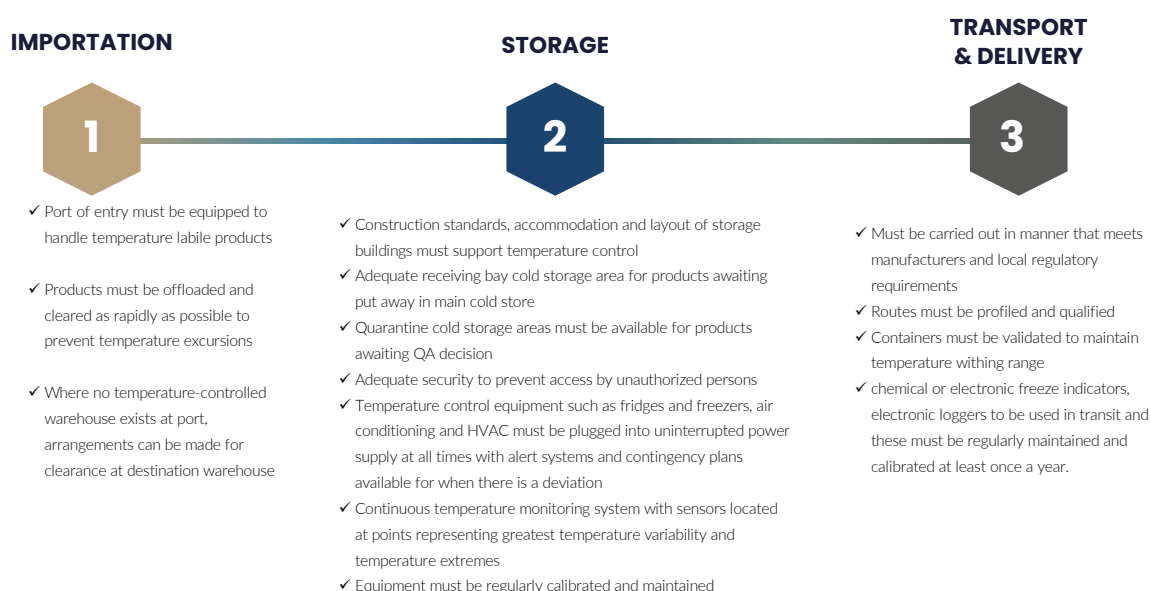


Figure 11: Diagrammatic overview of the structure of the procurement process in the public, private, and NGO/FBO sector

### 3.4.1 Cold Chain Logistics of Health Products and Technologies

Cold chain logistics encompasses the technology, strategic processes and people involved in the delivery of temperature sensitive health products and technologies to the end user. WHO defines a time and temperature sensitive health product as any health product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended. [35] Temperature sensitive health products range from pharmaceuticals, biological products (including vaccines), diagnostic media, breast milk substitutes, blood and blood components.

Each iteration in the supply chain is a risk for deterioration of quality and safety of a health product, therefore there is a constant need for innovative technology to maintain temperature within desired range during storage as well as transportation. A quality management system that continuously monitors and validates the cold chain system must be done, and guidance and output documents maintained in an up-to-date manner. The figure below summarizes the key quality assurance considerations at each iteration of product movement in the supply chain of temperature sensitive products.



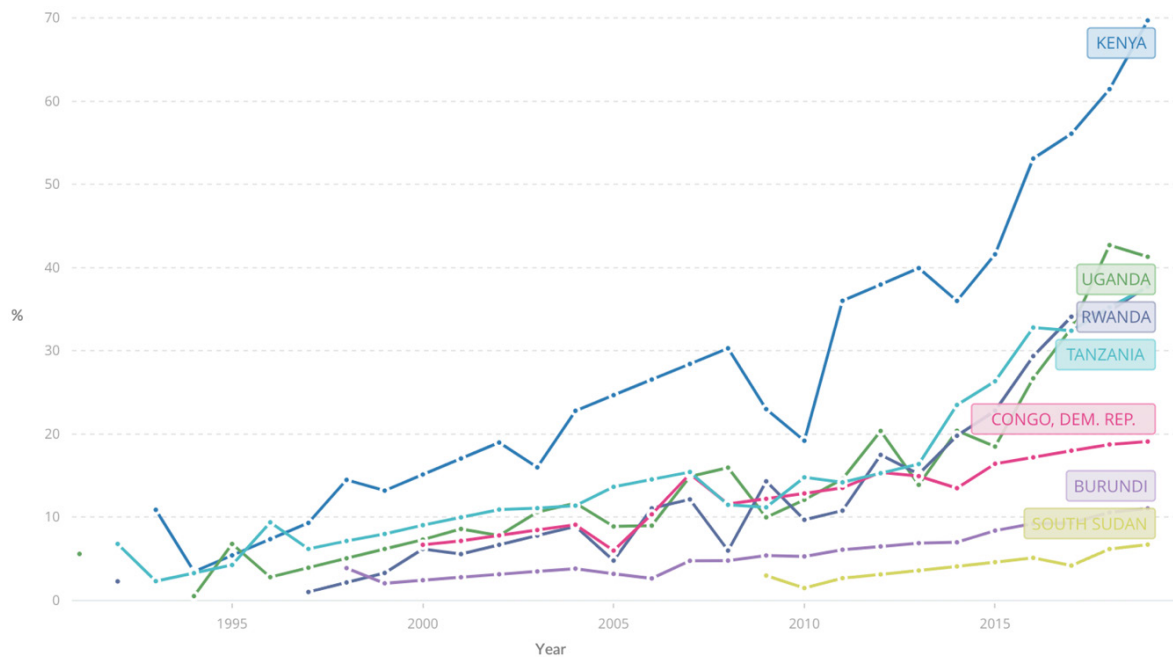
**Figure 12: Quality assurance considerations at each iteration of product movement in the supply chain of temperature sensitive products**

#### 3.4.1.1 Africa

Generally, cold chain logistics are quite underdeveloped in Africa, and capacity varies from country to country. Most cold chain equipment used for vaccines storage and transportation in sub-Saharan Africa are procured by UNICEF since majority of child immunization programs are sponsored by UNICEF and other donor agencies such as Bill & Melinda Gates Foundation and Global Fund. Countries then supplement this with their own purchases or from donations by philanthropists, foreign governments, multilateral agencies, and individuals. Inadequacies of cold chain logistics equipment persist particularly at the last mile, with the high cost of validated equipment and lack of or unreliable access to electricity being the main contributing factors.

27 out of 47 countries in Sub-Saharan Africa have less than 50% access to electricity [36] with 6 (six) out of 7 (seven) East African countries being in this category (see fig 8). [37] In rural areas, over 50,000 healthcare facilities lack electricity supply. [38] Active cold chain equipment such as freezers and

refrigerators require constant supply of electricity to keep vaccines and other medical commodities in good state. Lack of electricity connection means that the equipment cannot be used.



**Figure 13: Access to electricity (% of population) – Kenya, Uganda, Rwanda, Congo, Dem. Rep., Tanzania, Burundi, South Sudan**

Multilateral and bilateral donor support has been instrumental in upscaling of vaccine cold chain capacity on the continent. This support has been scaled up during the COVID-19 pandemic due to the increased need for cold chain capacity. In April 2021 for example, Vodacom Group and Vodafone Foundation donated €4.2 million<sup>1</sup> to for the purchase of cold chain equipment for ultra-low temperatures and technologies in Africa. The funds would be managed by African Vaccine Acquisition Task Team (AVATT). There are no updates on how the funds were used to boost the cold chain system in Africa or the recipient companies. In the same month, 25 African and six Latin American countries benefitted from an emergency grant of approximately USD 39 million from the Government of Japan through UNICEF for the development of cold chain systems. The recipient African countries were Kenya, Uganda, South Sudan, Somalia, DRC, Malawi, Mali, Ghana, Algeria, Angola, Cameroon, Djibouti, Egypt, Eswatini, Ethiopia, Guinea, Liberia, Libya, Mauritania, Mozambique, Nigeria, Senegal, Tunisia, Zambia, and Zimbabwe.

### 3.4.1.2 East Africa

While the member states of the EAC have a joint vision of attaining healthy and productive populations, their cold chain logistics are handled separately by their respective ministries of health and private sector players. There have been developments from regional and international organizations to boost the cold chain logistics in East Africa. In 2021, the African Development Bank approved \$10 million equity investment to boost the cold chain system of food and pharmaceuticals in the ARCH Cold Chain Solutions East Africa Fund (CCSEAF). The funds would be used to construct and operate eight cold chain operations in Kenya, Uganda, Tanzania, Ethiopia, and Rwanda.<sup>[39]</sup> The Republic of Germany contributed USD 34 million for vaccines and health supply chain management in the EAC. Cold Solutions Kenya Limited announced an investment of USD 70 million for the construction of modern, temperature-controlled cold storage warehouses in Nairobi and Mombasa. The long term goal is to establish end-to-end logistics in East Africa covering Kenya, Uganda, Rwanda, Ethiopia, and Tanzania.

<sup>1</sup> € 1 = KES 127.0935 (Central Bank of Kenya forex rate March 4, 2022)

### 3.4.1.3 Kenya

The bulk of cold chain logistics in Kenya comprises of vaccine logistics, a large part of which is childhood immunization vaccines. More recently the COVID-19 vaccine initiative has become a significant part of the logistics infrastructure with unique requirements that have put a strain on the existing cold chain resources.

The table below indicates the major importers, distributors and wholesalers handling cold chain health products and technologies in Kenya. At the importer/distributor level, they require large, insulated containers, preferably pallet sized and reusable. At the sub distributor wholesale level they require smaller containers such as 30cmx30cmx30cm that are reusable and they report challenges in temperature control using icepacks.

**Table 6: Major importers, distributors and wholesalers handling cold chain health products and technologies in Kenya**

Distributor	Category	Distributor	Category
<b>Private Sector</b>			
Philips Pharmaceuticals Group	Importer/distributor	Kavakava	Sub-distributor/Wholesaler
Surgipharm	Importer/distributor	Rangechem	Sub-distributor/Wholesaler
Harleys Limited	Importer/distributor	Gathimaini	Sub-distributor/Wholesaler
Sai Pharmaceuticals	Importer/distributor	Medisel K. Ltd	Importer/distributor
Nila	Importer/distributor/ wholesaler	Kulal International	Importer/distributor
Wessex Pharmaceuticals	Sub-distributor/ Wholesaler	Njimia Pharm.	Importer/distributor
Imperial Logistics	Importer	Madawa Pharm	Importer/distributor
Transwide Pharmaceuticals	Importer/distributor	Inkamed Pharm	Importer/distributor
Generic's Africa	Importer/distributor	Uzuri	Importer/distributor
Shell Pharm	Importer/distributor	Eldohosp	Sub-distributor/Wholesaler
Omaera Pharm	Importer/distributor/ wholesaler	Arachis	Importer/distributor
Laborex Kenya	Importer/distributor	McNaughton	Importer/distributor
<b>Public Sector</b>		<b>NGO/FBO Sector</b>	
KEMSA	Importer/distributor	MEDS	Importer/distributor

The following figure represents the vaccine logistics in Kenya, indicating that movement of commodities across the chain is largely similar in private and public sector but with some significant differences in data sharing i.e. movement of data from one step to the next and data visibility i.e. the degree of display, monitoring of data collected at the various steps in the chain.

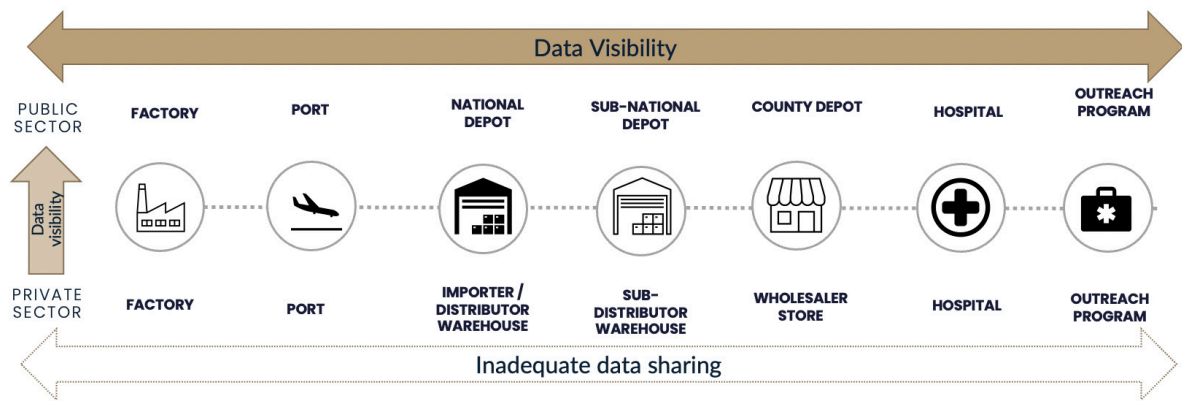


Figure 14: Overview of vaccine logistics in Kenya

An assessment done by the Ministry of Health, Kenya in 2021 for the deployment of COVID-19 vaccines found that there are 15 ultra-cold chain freezers. The National Vaccine store has eight cold rooms that have net capacity of 130M<sup>3</sup> for positive temperature cold storage (2-8°C) and 2 freezer rooms with a net capacity of 14m<sup>3</sup> for negative temperature cold storage (-20°C). These are enough for the storage of vaccines with quarterly distribution basis. At the moment, Kenya would have to procure cold chain equipment for the storage of medical commodities that require -70°C. The figure below shows regional stores also called sub-national depots for vaccines in Kenya. The figure also indicates the counties served by the subnational depots. <sup>[40]</sup>

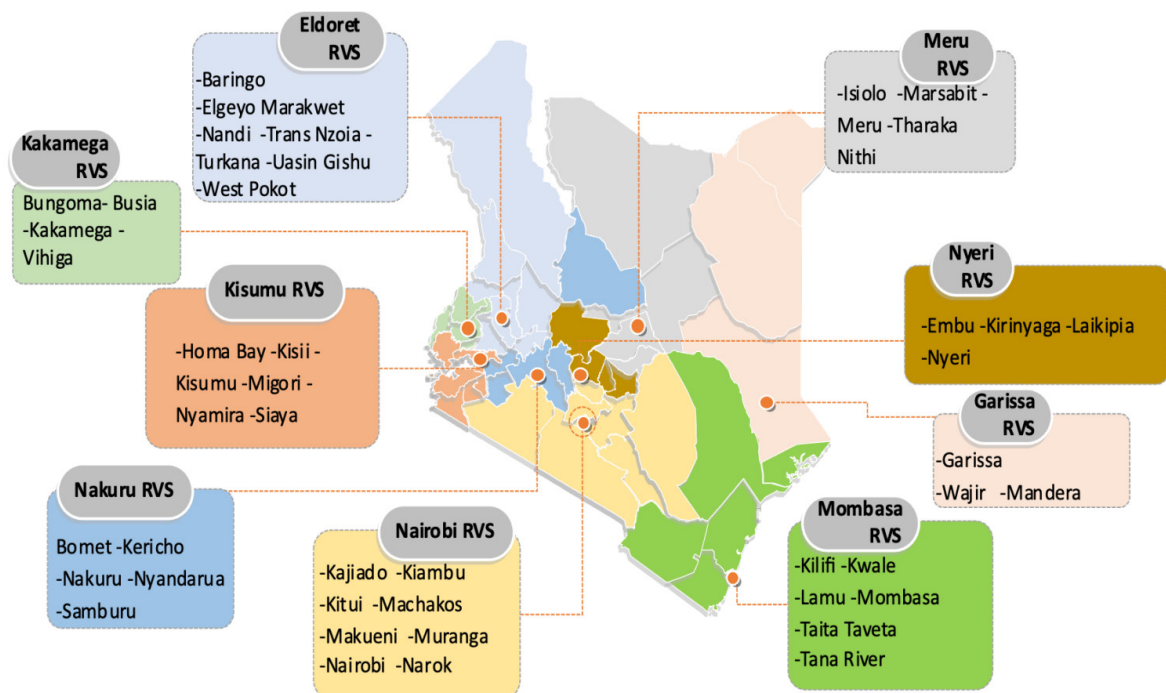


Figure 15: Regional stores in Kenya and the counties they serve






### 3.4.1.3.1 Snapshot of passive and active vaccine carriers used in Africa


Cooler boxes are insulated containers made of expanded polystyrene or plastic and used to store vaccines during transportation. Vaccine carriers are smaller than cooler boxes. They are lined with



coolant packs to keep vaccines cold during transportation. The vaccine carriers are available in various sizes and use coolant packs (gel or ice) to cool their contents during transportation.

**Table 7: Selected passive and active vaccine carriers used in Africa**

Vaccine carrier	Features
 <p data-bbox="172 633 443 741">This carrier is currently in use in hospitals in Makueni County.</p>	<p data-bbox="507 405 1337 958">A portable solar-powered fridge that was designed by a Kenyan to improve the storage and transportation of vaccines, pharmaceutical products, blood and blood products, and other medical commodities. VacciBox has a battery backup that can keep the fridge running for 12 hours. It can also run on grid power and battery. battery is detachable and can be used to power other devices in the healthcare facility. The temperature range in VacciBox is 2-10°C and it has a capacity of 40 litres. VacciBox is made of lightweight material and wheels to enhance portability and has a USB port for charging of communication devices to ensure the healthcare worker is connected with the rest of the team for easy collaboration and quick response in case of emergencies. VacciBox comes with a mobile application for real-time medical data management and a smartbox that collates and transmits medical data. In 2020, VacciBox won the Micro-Grid academy award and in September 2021, the first prize in Startup Energy Award.</p>
	<p data-bbox="507 992 1337 1249"><b>Eco-cooler</b> is a pre-qualified cold chain box manufactured by African Box Works, a cold chain packaging manufacturer that was established in 2012 in South Africa. There are different kinds of cold chain boxes, and they can also be customized to suit certain needs. The products are used in the transportation of pharmaceuticals and perishable that require certain temperature ranges to remain fresh. The market price for a 60L eco-cooler box is R1299, which is approximately USD 85.</p>
	<p data-bbox="507 1283 1337 1429">These cool boxes made of plastic or Styrofoam represent regular general use cool boxes that are not necessarily validated for pharmaceuticals and vaccines but that are in routine use in the last mile of vaccine delivery</p> <p data-bbox="507 1462 1337 1529">The market prices range between KES 4900 to KES 9400, which is approximately USD 49 to USD 94.</p> 
	<p data-bbox="507 1798 1337 2056">Pre-qualified by WHO and with a market price of USD 1,200 to 2,400 per unit, <b>Arktek Passive Vaccine Storage Device</b> can store vaccines upto - 80°C for six days and between 0°C and 10°C for more than 35 days without an external source of power. The 5L capacity carrier uses vacuum-technology and has a GPS monitor and sensors that store data that can be downloaded for quality checks. It has an alert system that allows for remote monitoring. It is in use in several African countries.</p>

Vaccine carrier	Features
	<p><b>Indigo cooler</b> is an innovation by Global Goods engineers at Intellectual Ventures Laboratory. It was unveiled in September 2017 for keeping vaccines at the right temperature for at least five days with no ice, no batteries, and no power required during cooling. The device needs heating so it can be used. When exposed to a source of heat, the water inside its walls evaporates and moves into a separate compartment. The Indigo Cooler can then sit on a shelf for months after heating ready to be used. When it is finally time to head out to the children, you open a valve, and the water starts moving back where it started. Because the pressure inside the Indigo has been lowered to the point where water evaporates at 5°C, the water particles take the heat with them.</p>

**Laafi Bag** is a smart bag that originated from Burkina Faso. It contains an isothermal box and a thermoregulation system that enables storage of vaccines in temperatures between 2 and 8 degrees for more than four days. The temperature can be controlled remotely. This project won € 10,000 (6,559,570 FCFA) in the Rebranding Africa Awards in Brussels and received a pledge of € 155,000 (CFAF 101,673,335) from Coris Bank Burkina Faso. African Development Bank (ADB) is financing part of the research for future development of the device.

### 3.4.1.3.2 Snapshot of third-party cold chain logistics companies active in Kenya and Africa

Logistics companies that transport medical commodities within and outside Kenya are fitted with cold rooms. The following table is snapshot of some of the major players in cold chain logistics

**Table 8: Selected third-party cold chain logistics companies active in Kenya and Africa**

Organization	Brief description
<b>Bollere</b>	Bolloré Logistics is operational in 48 African countries. Since the beginning of the pandemic, the company has been actively involved in the shipping of masks, test kits, and vaccines. The success of the transportation of commodities related to COVID-19 is overseen by the Task Force that was created by the company and comprises of hundreds of experts.
<b>DHL Kenya</b>	Provides 24/7/365 transportation and monitoring through air, ocean, and the road. The transportation options fall into three main categories: standard temperature-controlled air freight, temperature-controlled ocean freight, and medical express for time sensitive medical supplies. DHL offers transportation, management, warehousing, and integrated solutions.

Organization	Brief description
<b>Boxleo Courier &amp; Fulfillment Services</b>	Operational in Nairobi, Nakuru, Mombasa, and Kisumu. Serves pharmaceutical companies, hospitals, clinics, labs, blood donors, medical organizations and others to transport and track lab results, vaccines, blood samples, pharmaceuticals, equipment, and specimen of all sizes. The company has special compartments for storing patient records and packages for temperature sensitive products. Offers route, scheduled, rush, and refrigerated deliveries. Refrigerated deliveries.
<b>Transmeridian International Logistics Ltd</b>	Have refrigerated trucks and temperature-controlled storage for dry and liquid pharmaceuticals, medical diagnostics, reagents and devices and biochemical agents such as blood samples
<b>Freight in Time</b>	FiT has vast experience in clearing and forwarding of pharmaceuticals and medical devices incl. the regulatory requirements for imports and the exemption processing as well as spare part logistics for medical facilities. We are one of the few companies with expertise in final mile distribution of cold chain pharmaceuticals.
<b>Maersk</b>	A global logistics company whose East Africa hub is headquartered in Nairobi, Maersk has invested in specialised Pharma expertise, state-of-the-art equipment, and cold storage infrastructure. One in every four temperature-controlled containers in the world is a Maersk Reefer container. They offer pioneering visibility technology and their cold chain management integrates all supply chain activities through one point of contact.

## 3.5 COVID-19 pandemic and vaccination

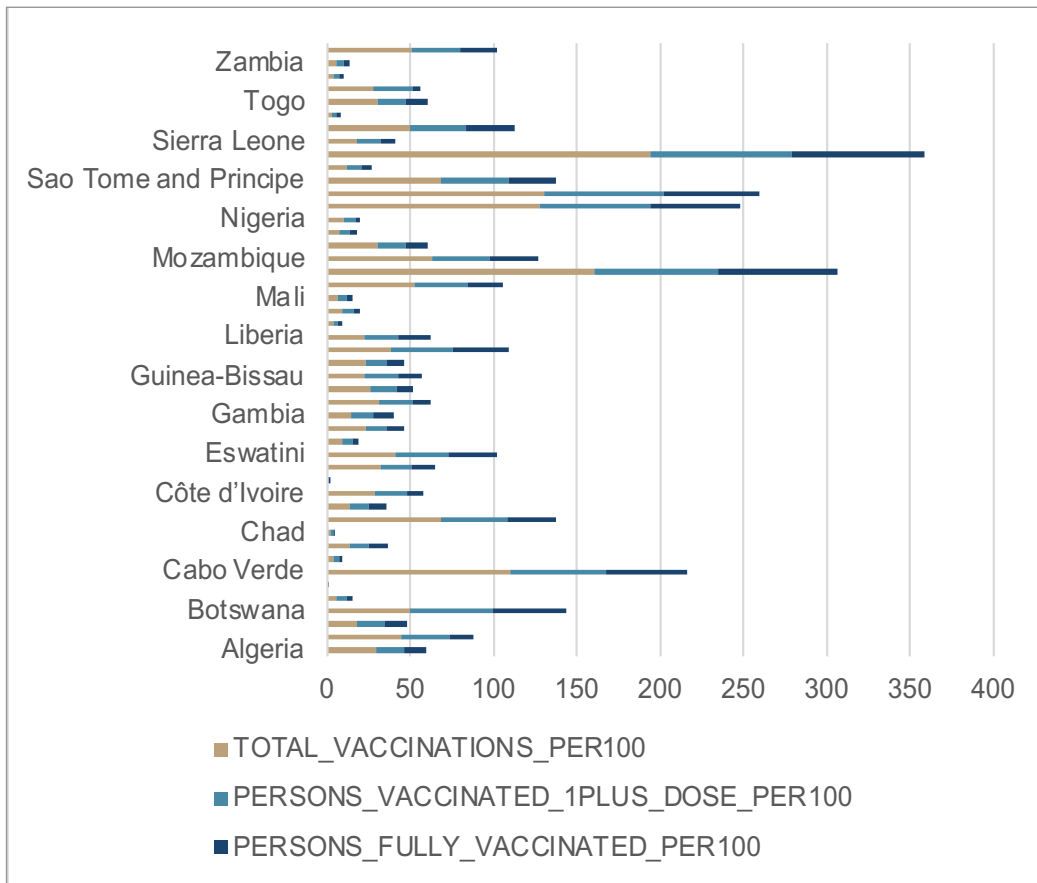
The first case of COVID 19 was reported in Kenya on 13th March 2020. Since then, a total of 321,335 cases and 5,580 deaths have been confirmed, giving a case fatality rate of 1.7%.

### 3.5.1 Vaccination drive

The introduction of COVID-19 vaccines globally in December 2020 marked a promising milestone to reverse the death toll of COVID-19 by limiting severe disease. Low- and lower-middle-income countries plugged into the subsidized COVAX and African Vaccine Acquisition Trust (AVAT) facilities to procure vaccines at a subsidized cost.

To help countries prepare for their COVID-19 vaccination drive, WHO rolled out a vaccine readiness assessment tool in November 2020. The African region scored an average of 33% readiness against a benchmark of 80% across the tool's assessment areas of planning and coordination, resources and funding, vaccine regulations, service delivery, training and supervision, monitoring and evaluation, vaccine logistics, vaccine safety and surveillance and communications and community engagement. <sup>[41]</sup>

Delayed access to vaccines due to global demand pressures, lack of locally produced COVID-19 vaccines, inadequate cold chain infrastructure, lack of funding to procure cold chain equipment and vaccines, and vaccine hesitancy have contributed to African countries falling short of their vaccination targets. The figure below shows the rates of vaccination in African countries by Feb 06, 2022. <sup>[42]</sup>



**Figure 16: WHO Africa Region COVID-19 vaccination data Feb 06 2022**

Kenya received the first consignment of COVID-19 vaccines in March 2021 but continued to experience delayed deliveries of vaccines despite plugging in to the WHO COVAX as well as the AVAT procurement facilities. Vaccine hesitancy was a concern at the onset of the vaccination campaign but later diminished due to the dual effect of sustained public health education as well as the disease dread imposed by the heightened death toll of Delta variant in mid 2021. The demand for vaccines outstripped the supply, with long queues witnessed at vaccination centres country wide, particularly in urban areas.

African countries (including Kenya's) access to vaccines improved in late 2021 at the same time as the deadly Delta variant wave subsided. Vaccine demand has now transformed from being driven by urgency to being driven by convenience, where people are more likely to get vaccinated if the vaccines are taken closer to them rather than them seeking the vaccines in health facilities. Through government measures in December 2021 prompted Kenyans to get vaccinated - over 2 million vaccines were administered in December 2021. Still, at the close of 2021 Kenya had only 15.5% of the targeted adult population fully vaccinated. <sup>[43]</sup>

As of 28<sup>th</sup> January 2022, the total number of Kenyans who had received the first dose of COVID-19 vaccines was 6,434,138 and 5,370,210 (19.7%) were fully vaccinated. <sup>[44]</sup> There are inequities in the reach and uptake of vaccines across the country, with the largest uptake being in urban areas. Nairobi County has the highest proportion of fully vaccinated persons at 39.2% with Tana River County sharply in contrast at the lowest position of 4.7%. In rural and remote areas, health facilities are few and far between, and the residents need to travel long distances to reach the health facility, leading to low uptake of COVID-19 vaccines.

**Table 9: Vaccine doses dispensed as at 28<sup>th</sup> January 2022**

Vaccine	Total doses Administered
Total 1st doses (All vaccines, >18yrs)	6,434,138
Fully vaccinated adults (>18yrs)	5,370,210
Booster doses	137,031
% of adults fully vaccinated	19.7%
Total doses	11,987,147
Partially Vaccinated 15-17 years	35,827
Fully Vaccinated 15-17 years	9,941

**Table 10: Distribution of 2nd dose and full vaccination status across the 47 counties in Kenya**

County	No. of adults fully vaccinated	Target population above 18	% of fully vaccinated adults
Nairobi	1,195,581	3,052,494	39.20%
Nyeri	187,680	510,028	36.80%
Laikipia	91,270	306,448	29.80%
Kakamega	267,835	982,838	27.30%
Kiambu	436,049	1,623,545	26.90%
Taita Taveta	55,234	213,335	25.90%
Nakuru	284,402	1,273,265	22.30%
Uasin Gishu	154,743	693,570	22.30%
Muranga	149,425	675,364	22.10%
Nyandarua	83,259	376,776	22.10%
Vihiga	72,623	329,317	22.10%
Kisumu	141,809	656,147	21.60%
Machakos	188,572	905,172	20.80%
Kirinyaga	85,219	413,708	20.60%
Bungoma	172,435	843,735	20.40%
Mombasa	162,250	804,202	20.20%
Embu	74,165	395,980	18.70%

County	No. of adults fully vaccinated	Target population above 18	% of fully vaccinated adults
Kajiado	123,218	663,201	18.60%
Siaya	97,058	536,031	18.10%
TransNzoia	87,707	518,077	16.90%
Nyamira	57,589	341,397	16.90%
Kericho	84,182	508,980	16.50%
Tharaka Nithi	40,473	246,699	16.40%
Meru	147,519	949,186	15.50%
Elgeyo Marakwet	36,932	243,690	15.20%
Lamu	12,229	83,433	14.70%
Makueni	84,754	584,754	14.50%
Busia	63,552	465,190	13.70%
Migori	72,461	557,657	13.00%
Nandi	63,774	492,652	12.90%
Baringo	43,114	338,937	12.70%
Kisii	86,185	697,445	12.40%
Homabay	68,374	608,326	11.20%
Kwale	45,457	451,261	10.10%
Samburu	14,474	145,608	9.90%
Kitui	57,139	624,506	9.10%
Isiolo	11,507	133,358	8.60%
Kilifi	59,732	784,567	7.60%
Bomet	34,625	465,963	7.40%
Narok	39,861	548,229	7.30%
West Pokot	20,566	283,727	7.20%
Garissa	28,293	399,358	7.10%
Marsabit	14,864	219,170	6.80%
Mandera	20,782	341,857	6.10%

County	No. of adults fully vaccinated	Target population above 18	% of fully vaccinated adults
Turkana	26,642	468,878	5.70%
Wajir	17,476	337,296	5.20%
Tana River	7,120	151,051	4.70%
<b>Total</b>	<b>5,370,210</b>	<b>27,246,033</b>	<b>19.70%</b>

To sustain uptake of vaccines and achieve vaccine equity, it is now more necessary than ever to take vaccines to people rather than wait for people to come to vaccines.

### 3.5.2 Lab testing

COVID-19 testing is conducted in laboratories that have been authorized by the Ministry of Health in private and public sector. The cost of testing is KES 1000 (approx. USD 10) in public health facilities, while in the private sector, the price ranges from USD 25 to USD 100. COVID-19 testing has been advanced by WHO as key to pandemic control. The COVID-19 laboratory test rate in Kenya currently stands at 67,709.6 samples per 1,000,000 people. <sup>[45]</sup> Outreach testing has proven useful in estimating disease burden and prevalence and spread. This requires personnel and sampling equipment to be taken to communities rather than waiting for the community to come to the health facility.

### 3.5.3 Data management solutions

The supply chain of medical commodities is data driven. Data management solutions for medical supplies take different configurations depending on the needs of users and the resources available. Whilst high end private healthcare facilities have invested in sophisticated data management solutions, the same is not so for resource constrained facilities. Resources needed to procure and maintain data management systems for the health supply chain are financial and human resources such as data analysts and tech experts who keep track of the facility's performance metrics.

In any case, an ideal data management system should be user-friendly to eliminate barrier for use by the designated personnel, have optimal data matching and linking capability to ensure accurate reporting, and hold volumes of data depending on the need without posing technical challenges. In addition, a data management system should allow localization of data for easy access by authorized personnel whenever they need to, ensure data protection and privacy, be flexible to facilitate upgrades, be reliable, and give business process insights.

Kenya is currently using Chanjo, an electronic logistics management information system ([portal.go.ke](http://portal.go.ke)) for the management of data for COVID-19 diagnostics, therapeutics, and vaccine logistics. The system has a dashboard that shows performance indicators showing the number and type of doses received, batch numbers, doses used, balance, and total number of people vaccinated. It is also acting as an end-to-end self-service portal connecting the Ministry of Health and the public. The Ministry of Health leverages the procedures provided by UNICEF under the Vaccine Independence Initiative Agreement to expedite logistics from the port of entry to the central vaccine stores, on to the regional stores and to the last mile where the patient received the vaccines.

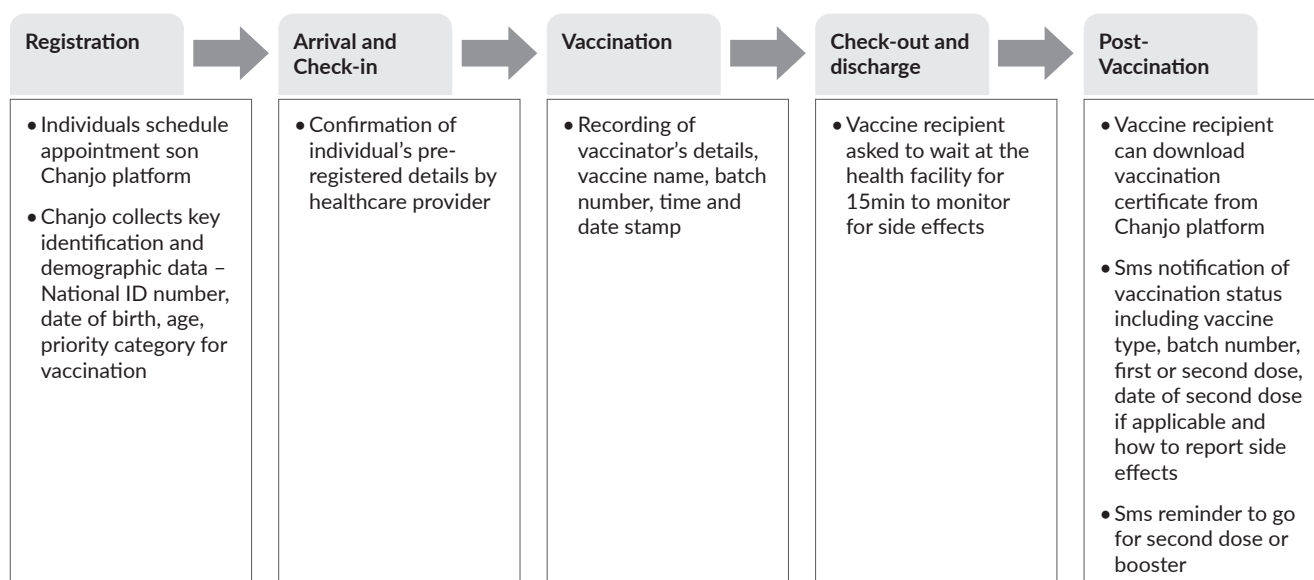


Figure 17: Process of receiving a vaccine in Kenya

## 4 Gaps and opportunities in the health products and technologies cold chain ecosystem in Kenya

### 4.1 Gaps

- a) **There is a significant need for last mile portable cold chain carriers in both private and public sector.** It is preferred that these carriers do not depend on electricity all the time, are solar powered, and are not ice based.
  - i) The cool boxes that are currently being used in some counties are bulky and still use icepacks hence the commodities medical boxes being transported are susceptible to breaking.
  - ii) Many logistics companies that have invested in state-of-the-art cold chain storage and transportation capacity only deliver to the first and second mile, i.e. from factory to importer's warehouse and on to distributor's or wholesaler's warehouse.
- b) **There is a need for first- and second-mile cold chain containers in private sector.** Reusable containers are preferred because of low cost in the long run and because of their more favourable environmental impact compared to single use containers. The public sector vaccine supply chain is currently well served with insulated containers and fridges for the first and second mile of vaccine transport and storage. These are provided through UNICEF with funding from GAVI and other donors.



- c) **There is a need for end-to-end data management systems for health commodity supply chain management in the counties.** It is preferable if these systems are interoperable with the Kenya Health Information System.
- i) Some healthcare facilities at the community level are still using pen and paper to keep record of movement of commodities. Tracing of such manual data is not only time-consuming and physically taxing, it also results in erroneous data being uploaded to the national HIS.
  - ii) Some facilities do not have storage rooms for the files and if the space is exhausted, after a while, they might decide to discard old files or bypass daily records or overlook record keeping altogether. This impacts the usefulness of business decisions that must be made based these data. Medical facilities are expected to make monthly updates to the HIS, and if the process of collating, aggregating and submitting the data takes too long, those at the national level are at risk of making ill-informed and wrong decisions.
  - iii) In other instances, the data, though collected, remains invisible and unanalysed and therefore not useful to inform any business or policy decisions.
- d) **There is a need for more awareness and education about how to preserve vaccine efficacy, minimize vaccine wastage, and about the dangers of using ice-based solutions in vaccine storage and transport**
- i) The supply chain requires a lot of human capital across the entire value chain. Inadequacy at any level means that some activities will be delayed or not done to a satisfactory level. Many staff handling health commodities are not sufficiently trained in supply chain management including cold chain management. It is not unusual to find that health professionals such as nurses, medical officers, and hospital administrators are handling logistics of medical commodities. Already overwhelmed by their every-day duties and more so now with COVID-19 vaccination efforts, the additional workload adds a risk of poor management decisions by the health workers.
  - ii) Hard to reach remote areas need even more care to be taken to maintain vaccine efficacy as these are the areas with very hot climate. These regions also present the longest distances to be covered to take the needed vaccines to the population.
  - iii) Many community-level medical facilities do not have a technician for routine maintenance of medical equipment used in cold chain transportation and storage of vaccines. This role is taken up by health professionals in the facilities, who may have little-to-no information about the technical aspects of the cold chain device.
- e) **There is a need for portable cold chain containers that have inbuilt temperature monitoring.** It is preferred that these monitors give alarms when temperatures are out of range, and that they are fitted with inbuilt GPS for remote monitoring.
- f) **There is a need for more allocation to health budgets in counties.** Counties get allocated vaccine carriers and fridges by the National Ministry of Health. However, the allocated equipment is not enough to reach the last mile. Counties then are compelled to procure for themselves supplemental carriers and because of low budgets they buy ice-dependent passive carriers that put the cold chain health products at risk of temperature excursions.

### Responses from key informants:

Some facilities do not report the use of their medical commodities. We are encouraging a culture of using data in the supply chain using the slogan, "no data no commodities."

We don't have enough temperature data loggers.

We have vaccine tags that we insert in the cool box. These only give an indication of high temperature but not freezing.

We use the matatus that are used for transporting everything else and they can be quite chaotic. I am yet to come across a logistics company that is exclusively offering services for the medical sector in Kenya.

- We buy our cold boxes from general supermarkets. Since there is no one to customize them for our use, we must be creative to see how they will serve us. This is not easy.
- Our refrigerators and freezers are currently fully stocked with COVID-19 vaccines. If we need to store other medical products, we will have to seek assistance from others and if there is none, then the supply chain will be interrupted.
- Pharmaceutical distributor: we supply our products to clients who are throughout the country. If they do not have enough storage space to keep delivered commodities, we return the products to our warehouses. Sometimes the distance is long, and if we do not have enough ice packs and other cooling products, then there is a risk of the commodities being destroyed. If we are using the normal transportation means, then the risk is even high because they can be mishandled. Another challenge is that we only have one distributor of ice packs in Kenya.

We have our portable cold chain transport containers custom made for us by our South Africa office. We cannot get the same here in Nairobi. We prefer reusable containers because they last five years, and even through the initial cost outlay is high, when it is spread over 5 years it is cheaper than single use containers.

We rely heavily on the cold chain equipment provided by National government. But when we pick the vaccines from the county depot, we place them in ordinary cool boxes and place them in non-temperature controlled vehicles. The distances to some health centres are very long. And we get concerned about the temperature in case we are not able to finish the vaccines in a day. We manage this by only carrying few doses per trip to avoid wastage. This is not efficient.

## 4.2 Opportunities

The following figure indicates the areas in the supply chain where the 3 innovations (Celsure, Emvolio and AWL system) are required in the Kenyan health supply chain:

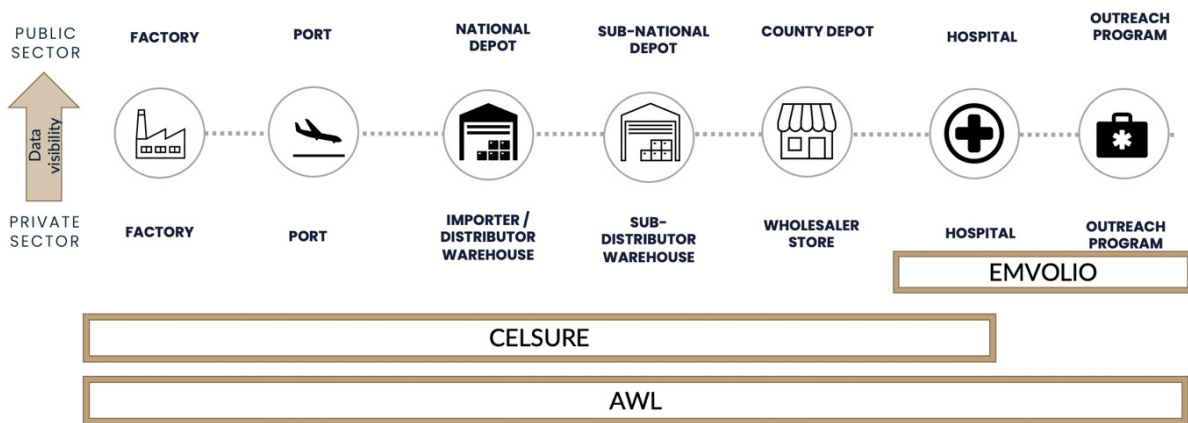


Figure 18: Areas in the supply chain where Celsure, Emvolio and the AWL system are required in the Kenyan health supply chain

### 4.3 Recommendations

1. Make available passive and active cooling devices that operate without electricity partially or completely, to improve for storage and transportation of drugs, vaccines and other temperature sensitive biological substances to the last mile. There should also be readily available after-sales service for the devices.
2. Design vaccine carriers or cool boxes with sturdy and lightweight material and temperature monitoring systems. Such boxes should be sold at a friendly price and should be reusable
3. Establish medical logistics companies that deal in cold chain transportation to the last mile
4. Take advantage of the **Africa Medical Supplies Platform (AMSP)** that was established to provide consumers immediate and easy access to a wider range of African and global base of vetted manufacturers and procurement strategic partners. This digital platform also enables African Union Member States to purchase certified medical equipment such as diagnostic kits, PPE, and clinical management devices at a relatively lower cost and provides for increased price transparency. The platform serves as a unique interface enabling volume aggregation, quota management, payment facilitation as well as logistics & transportation to ensure equitable & efficient access to critical supplies for African governments.
5. Engage private importers, distributors and wholesalers directly through structured business to business meetings that lead to purchase commitments
6. Set up a local center for queries and maintenance of vaccine carriers
7. Engage Kenya Medical Supplies Authority, the Vaccines program at Ministry of Health Kenya and county departments of health through the county directors of health to enter the public sector. This will entail incorporating the description of the 3 products in the tender documents.
8. Engage MEDS to procure the 3 products for their clientele which comprises mainly faith-based hospitals
9. Ensure that solutions such as Celsure and Emvolio undergo preshipment verification of conformity assessment before any shipment to Kenya.

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# 5 Methodology

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This study was undertaken through desk-based research, and either virtual or in-person Key Informant Interviews (KIIs). For the desk-based research, the team conducted an extensive literature review based on relevant journal articles, reports, regulatory documents, statutes, standards, studies, government policies, strategies, and country profiles in addition to regional and international initiatives. The information obtained in the literature review was used to guide the interview data collection and a customized interview guide with both qualitative and quantitative components was developed. The desk-based research is referenced in the footnotes at the end of every page of this document. The information gathered was validated and or expanded during the interviews with key stakeholders in the various industries involved in this project.

The scope of the study was Kenya, with some data from East Africa and Africa included for context. 15 interviews were conducted with key informants who are involved in vaccine logistics, laboratory diagnostic samples logistics and supply chain data management. The informants were drawn from government (MOH), healthcare providers, as well as public and private sector distributors of health products requiring cold handling.

## 5.1 Limitations

The study posed three main challenges. In desk-based research, the consulted resources did not inform all questions on cold chain logistics in Africa. There is lack of reliable and centralized data showing the status of cold chain logistics in different African nations and the respective needs and the improvements happening where support was offered. There were many statements of donations and procurement of cold chain solutions and no way of knowing if they were effective. Some reports on cold chain used ambiguous terms such as “underdeveloped system”, “insufficient supply of cold chain equipment” and “the system needs improvement” without quantification of the needs. The challenge encountered during interviews was the availability of key respondents which made the study take longer than anticipated. In addition, all interviews were conducted online, which could have affected the transparency of the respondents to the questions. In cases where opinions were given, there was no way of verifying whether the information was factual.

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# 7 Annexes

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## 7.1 Regulatory Landscape of Insulated Shipping Containers

### 7.1.1 WHO Requirements

#### 7.1.1.1 Guidelines on qualification of shipping containers

The WHO guidelines on the qualification of shipping containers are intended for use by any party responsible for maintaining quality during the process of assessing, procuring, and using Time and Temperature Sensitive Pharmaceutical Product (TTSP) shipping containers systems. These parties should be able to appreciate and understand the importance of pharmaceutical product temperature stability, have a good working knowledge and understanding of the necessary applicable logistics and transportation methodologies within their organizations, in addition to understanding the basic concepts of packaging thermodynamics.

Qualification refers to an inspection and testing process used to establish that a piece of equipment or a physical installation is fit for purpose in the operational context within which it will be used. There are typically three stages in the qualification process. Each of these stages must be successfully completed before commencement of the next one. These stages include:

- a) **Design qualification (DQ):** In this first stage, the manufacturer of the product is required to establish using laboratory testing under tightly controlled conditions, that a specific item of equipment performs in accordance with the user requirements specification (URS). Although the design qualification demonstrates compliance with the URS and the associated test protocols; it is not considered conclusive proof that the equipment will be suitable in a specific operating environment because the URS and the test procedures are will not necessarily reflect the full range of operating conditions.
- b) **Operational qualification (OQ):** This is the second stage where the manufacturer establishes, through further documented testing under controlled conditions, that the equipment is likely to perform as intended in the operating environment in which it will be used.
- c) **Performance qualification (PQ):** In this stage, documented testing is carried out to establish with a high degree of assurance that the equipment together with all associated systems, certainly performs as intended under routine operating conditions in the environment in which it is intended for use.

If the container manufacturer can with proof demonstrate that the product has already passed an appropriate conformity assessment or that it is already independently prequalified by a standard setting organization such as WHO, the DQ stage is not required. In both these cases design qualification will have formed part of a pre-purchase assessment process. A list of all WHO prequalified products related to cold boxes, vaccine carriers, and other insulated containers used in the transport and/or storage of vaccine is made transparent on the **WHO website**.<sup>[46]</sup> Additionally, if the system manufacturer can supply a satisfactory OQ report which meets the end-user's needs, the OQ stage may also not be needed.

Individuals or organisations which are mandated with the responsibility to conduct the qualification testing must be capable of operating the equipment necessary to complete the tests and be familiar with and follow, good laboratory documentation practices. Prior to any qualification stage, it is highly recommended to carry out a risk assessment to identify the environmental conditions and the

distribution lanes through which the proposed container will travel. This process helps ensure that the proposed qualification procedure will match the intended use. It is equally advisable to consider the anticipated scenarios when deciding on the qualification temperature ranges.

Comprehensive details of the packaging assembly must be defined, tested, and documented for each of the three stages of the qualification process. These details include but not limited to the thermal conditioning regime for system components and the products being transported, product loading arrangements and the location of temperature monitor(s). The various test dates should also be recorded clearly in all qualification reports.

It is also strongly recommended to test both the minimum and maximum product loads at each of state of the process. Ideally, the test loads should be selected to represent the products which will be transported. Often, the lowest thermal mass products are the ones which are found to be the most susceptible to temperature change. Accordingly, the minimum load in a test should represent a shipment of a minimum quantity of lowest thermal mass product and the maximum load should represent a full payload of this same product.

Qualification must also take account of the transport route(s) and modes of transport and the anticipated ambient temperature profile over the duration of transport. The duration taken during transportation is measured from the time the completed package is closed and sealed at the point of departure, until the package is opened at the point of arrival in the recipient's temperature-controlled store.

#### **7.1.1.1.1 Pre-qualification of cold-chain related products under the WHO PQS system**

If a manufacturer is granted the PQS pre-qualification status, it does not constitute a guarantee of purchase. Successful pre-qualification is only but an indication that the product is technically satisfactory for procurement by United Nations Agencies for the purpose for which it is intended, and subject to any limitations as set out in the PQS database or catalogue.

Manufacturers of these products are entirely responsible for making commercial arrangements with potential purchasers and for ensuring that the quality of the delivered product is acceptable to that purchaser. Any one of the UN agency procurement units, including UNICEF, IAPSO, UNFPA, and WHO can be a purchaser. Applicants must also be aware that individual UN procurement agencies reserve the right to impose additional conditions and limitations when seeking submission of tenders for the supply of pre-qualified products listed.

Manufacturers or distributors who wish to be enlisted writes to the PQS secretariat providing the information below:

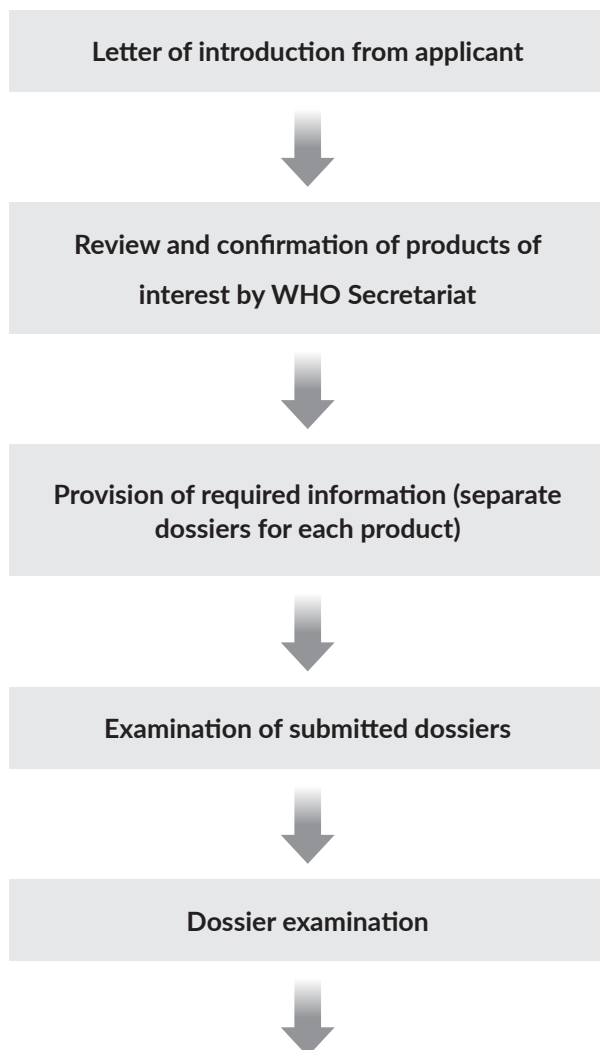
- contact name, address, telephone number and email address
- technical details and photographs of the product or product range being offered specifying which of the PQS performance specifications the product can meet
- concise details of the location and capacity of the manufacturing site (s)
- if the application is from a pre-seller, full details of a contractual relationship with the legal manufacturer of the product(s) being offered.

At this point, applicants are not required to send separate comprehensive dossiers for each of product. This is because once the introductory letters have been successfully received, the secretariat writes back to confirm which of the products presented are of interest to the organisation and have been approved for evaluation. The secretariat will also provide the applicant with a list of all information to be submitted to make a formal application for pre-qualification. In the case that the secretariat considers any of the products unsuitable, it will be communicated in due time to the applicant. A non-refundable fee is charged for each product dossier submitted for an initial evaluation of a product dossier. If a product is pre-qualified, an annual re-evaluation fee will also be incurred by the respective applicant.

Envelopes or packages should be clearly marked: PRELIMINARY PQS PREQUALIFICATION APPLICATION and addressed to:

PQS Secretariat  
Department of Immunization, Vaccines & Biologicals/QSS  
World Health Organization  
CH-1211  
Geneva 27  
Switzerland

Below is a summary of the pre-qualification procedure followed by WHO





**Sending samples of the products to a WHO-accredited testing laboratory for evaluation against the relevant PQS verification protocol (laboratory fee incurred by the applicant)**



**Review of the verification report (copy sent to the applicant) where the PQS Steering Group will recommend whether the product has been pre-qualified or not**

In-order to maintain the pre-qualified status, the performance of the product(s) is kept under continuous review through the formal PQS review procedure as well as the procurement process at the various UN procurement agencies. It is critical to note that failure to report changes made to the product, the manufacturing process, or the manufacturing site will lead to immediate loss of the pre-qualification status. Annex 2 provides checklists of all information required throughout the pre-qualification process.

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### **7.1.1.1.2 WHO pre-qualification checklists**

#### **7.1.1.1.2.1 Preliminary application checklist**

**Refer to Section 3.5 – Have you included the following?**

1. Covering letter.

2. Contact details

3. Technical details of each of the products that you are offering for evaluation.

4. Photographs of each product.

5. Details of the PQS performance specification against which you want us to assess the product.

6. Brief details of each of your manufacturing sites.

7. Confirmation of the production capacity of each of your manufacturing sites.

8. If you are a reseller, provide details of your contractual relationship with the legal manufacturer of the product(s) you are offering.

Provide this information in a correctly labelled and addressed envelope/package OR formal electronic submission in PDF or JPEG format.

### 7.1.1.1.2.2 Dossier submission checklist

**Refer to Section 3.6 - Have you included the following items for each product and for each manufacturing site?**

1. A covering letter.
2. A countersigned copy of the letter of invitation to submit received directly from WHO.
3. The correct Dossier Examination Fee, in US dollars.
4. Product sample(s) where listed in Section 7 of the PQS performance specification applicable to the product you are offering.
5. Product sample(s) where listed in Section 7 of the PQS performance specification applicable to the product you are offering.
6. A completed Product Summary Sheet Questionnaire and all relevant attachments (see Annex 5.3 and associated notes)

### 7.1.1.1.2.3 Annual review checklist

**Refer to Section 3.12.2 - Have you included the following items for each prequalified product and for each manufacturing site?**

1. A covering letter showing clearly the product to which the dossier refers.
2. The annual re-evaluation fee in US dollars.
3. Certified photocopies of time-expiring documentation that you have renewed since you made your last submission. If none, confirm this.
4. Details of changes to the company name or status (for example, if you have been taken over by another company). If none, confirm this.
5. Details of changes to the manufacturing site since you made your last submission. If none, confirm this.
6. Details of changes to the manufacturing process since you made your last submission. If none, confirm this.
7. Details of changes to the system components since you made your last submission. If none, confirm this.
8. Details of all significant component and/or installation failures reported to you during the past year. If none, confirm this.
9. Progress report on the resolution of any problems reported to you by the PQS Secretariat. If none, confirm this.
10. A list of other matters that you wish to draw to our attention. If none, confirm this.

### 7.1.2 National Pre-export Verification of Conformity (PVoC)

The PVoC is a pre-export verification of conformity to standards set by national bureaus of standards in different countries. It is a conformity assessment procedure which is applied at the country of supply or origin to ensure compliance of imported products with applicable standards, approved specifications, and regulations.

Through their independent national bureaus of standards or the responsible bodies, the EAC partner states enforce the PVoC to ensure the quality and safety of goods imported into their countries. The overall objective is to protect consumer health and safety as well environment in addition to promoting fair trade practices.

In Kenya a Pre-Shipment Verification of Conformity (PVoC) for any products being exported into the country is mandatory. Exporters of any products into Kenya are therefore expected to ensure that their products or goods meet the set regulations and quality requirements before shipment. This can be accomplished through carrying out relevant tests based on the specific Kenya Standards or approved specifications and/or obtaining the necessary Certificate of Conformity (CoC) from approved PVoC agents for all products that are subject to the PVoC program.

The Kenya National Bureau of Standards (KEBS) has contracted six inspection companies or PVoC agents to conduct the PVoC activities. These companies include Messrs Bureau Veritas, Cotecna, China Certification & Inspection (Group) Inspection Co. Ltd, Intertek International, SGS and QISJ. Their main role is to perform conformity assessment activities in the country of origin for all products being imported into the destination country. These activities include inspection, sampling, testing, sealing of full-load containers, issuance of COCs /COIs /CORs, and any other as deemed necessary in accordance with the standards.

It is also key to note that the importation of machinery and equipment which are classified as equity capital or loan purchases must be received prior to exchange approval. This is because local banks in Kenya will not issue shipping guarantees for the clearance of imports in the absence of such an approval. All imports procured by Kenyan-based importers must be insured with insurance registered companies fully licensed to conduct business in Kenya.

### 7.1.3 Registration as a medical device


Vaccine carriers and fridges in Kenya are not yet subject to registration as medical devices. However, because they are borderline products that can be posited to be medical devices or non-medical devices at the time of import, a manufacturer or distributor of these products can opt to register them as **class A** medical devices.

The market authorization, also referred to as the registration process, takes three to six months and the requirements are prescribed by the **Pharmacy and Poisons Board**.

**Application is done through an online portal. If the applicant is not legally present in Kenya, they must appoint a local technical agent who is present in Kenya who shall submit product application dossier to PPB.**



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