Federal Ministry
for Economic Cooperation
and Development

giz

Smart logistics for medication

IMPROVING ACCESS TO MEDICINES AND DIAGNOSTICS IN KENYA

Research report for the lab of tomorrow - May 2016

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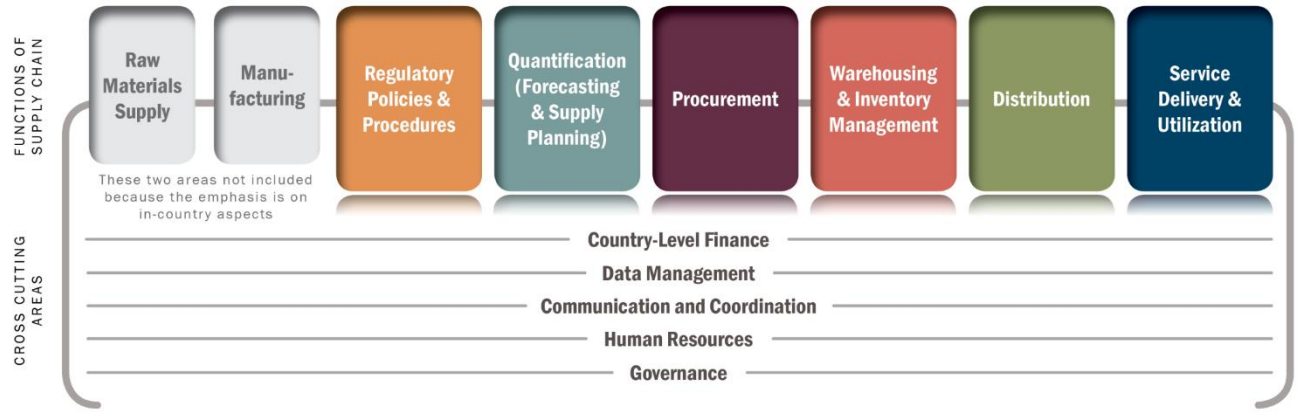
Acronyms

ART	Anti-retroviral therapy
BMI	Business Monitor International
CHAI	Clinton Health Access Initiative
COMESA	Common Market for Eastern and Southern Africa
EAC	East African Community
FBO	Faith-based Organisation
GFATM	Global Fund to fight AIDs, Tuberculosis and Malaria
GOK	Government of Kenya
ICT	Information and Communication Technology
IMF	International Monetary Fund
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KMOH	Kenyan Ministry of Health
MDGs	Millennium Development Goals
MEDS	Mission for Essential Drugs and Supplies
OEM	Original Equipment Manufacturer
OTC	Over-the-counter
PPB	Kenyan Pharmacy and Poisons Board
SADC	Southern Africa Development Community
SDGs	Sustainable Development Goals
WBG	World Bank Group
WHO	World Health Organisation
UNICEF	United Nations Children's Emergency Fund
USAID	United States Agency for International Development

Definitions

Supply Chain System and Definitions[1]



Cold Chain: a temperature-controlled supply chain that maintains the product within a given temperature range throughout.

Forecasting/ Quantification: the process of estimating the quantities and costs of products required for a specific health programme (or service) and determining when they should be delivered to ensure an uninterrupted supply.

Informed Push Model: a distribution model that adapts principles used in commercial distribution to the public health sector, where a driver with a shipment of supplies visits each point of sale on a regular schedule to refill the stock and record quantities of products sold. Data collected by the driver is used to ensure that there is sufficient stock at the warehouse and at each site, and to prime the manufacturers to keep pace with demand.

Logistics: the technical process of getting a product through the supply chain from the manufacturers to the consumers. Logistics activities are broken down into the operational components of the supply chain management - quantification/forecasting, procurement, storage/warehousing, transport, inventory management, and information systems - and focus on specific tasks within a particular health system programme.

Stock-out: when supplies have been exhausted and are not available according to shipment plan, or when patients are turned away or referred to other facilities to acquire needed health products.

[1] GAVI Supply Chain Strategy Evidence Review Report, JSI Deliver, Intrahealth

Supply Chain: a system of organisations, people, activities, information, and resources involved in moving a product from the point of origin (manufacturers) to the point of use (consumers). Also referred to as Supply Chain Network.

Supply Chain Management: the active management of the supply chain encompassing the planning and management for logistics, as well as the logistics activities, and the coordination and collaboration of stakeholders involved in the supply chain.

1. Introduction

The Kenyan Ministry of Health aims to attain equitable, accessible, and quality healthcare for all and recognises the importance of building a progressive, responsive, and sustainable healthcare system. Despite significant improvements of health outcomes in Kenya, many challenges still exist that disproportionately affect the most vulnerable populations. This includes those living in extreme poverty who cannot afford medicines or diagnostic procedures, and those living in remote, rural areas and conflict zones, where access to essential medicines is low. Shortages of medicines and other health products not only lead to poor health outcomes, but also have an economic and social impact on the country overall.

The *GIZ Lab of Tomorrow – Improving access to medicines and diagnostics in Kenya,* is looking to explore the key challenges related to the accessibility and affordability of healthcare for such vulnerable populations, and explore and develop innovative, sustainable business-driven solutions together with European and African stakeholders that can overcome substantial hurdles along Kenya's pharmaceutical supply chain. Inefficient logistics services affect economic growths, congestion and road safety. Transforming logistic services in a sustainable, innovative manner can improve the efficiency of goods distribution, reduce energy consumption and emissions of freight vehicles and contribute to the overall efficiency of supply chains.

This report compiles personal experiences, research and interviews to provide context to the challenges, as well as initiatives that are taking place in the country to inform participating stakeholders for solutions development.

2. Background

Country profile

Capital:	Nairobi
Area:	580,000 sq km
Total Population 2013:	44.4 Million
Urban Population 2013:	24.78%
GDP:	US$ 44.9 Billion
GNI Per Capita 2013:	US$ 860

General Information

Kenya has an estimated population of 44.4 million, and it is increasing by about one million each year. The population is very young with 42% under the age of 15 and a life expectancy of 63.5 years. Just over one quarter of Kenyans lives in urban areas.[3] The country has a very diverse geography with a coastline along the Indian Ocean, swamplands, rainforests, plains, hills, and mountainous regions. Respectively, the climate varies with large parts of the country experiencing a tropical savanna climate, warm semi-arid or warm desert climate. Only 20% of the entire Kenyan population has access to reliable electricity and only 5% of the rural population has access.[4] 42% of the population has access to a consistent, safe water supply.[5]

Political Context

Devolution, the decentralisation of government funding and services to bring the Government closer to the people, is considered the biggest gain from the 2010 constitution, which ushered in a new political and economic governance system. It is transformative and has strengthened accountability and public service delivery at local levels. The Government's agenda is to continue the implementation of devolution and strengthen governance institutions while addressing other challenges, including land reforms and security to improve economic and social outcomes, accelerate growth and equity in distribution of resources, and reduce extreme poverty and youth unemployment.

Economy[10]

According to Kenya's National Bureau of Statistics, Kenya's economy grew by 4.9% in the first quarter of 2015, compared to 4.7% in the same period in 2014. Agriculture, manufacturing, investment in infrastructure, lower energy costs, improved financial services, and information and communication technology (ICT) contributed to this growth, while manufacturing and tourism declined. A stable macroeconomic environment, continued investment in infrastructure, improved business environment, exports, and regional integration will help sustain this momentum.

The GOK has also maintained fiscal and monetary discipline, despite increasing pressure from the devolution process and rising public sector wages. Total public debt has increased but remains sustainable, according to Central Bank figures; inflation and interest rates remain stable. The stock exchange weakened due to net foreign investor sales, while the Kenya shilling (KES) weakened against the US dollar.

With increased competition in manufacturing, which is projected to be a key driver of growth, export, and job creation, Kenya is emerging as one of Africa's key development centres.

Social Development

[3] UNDESA, 2014 World Urbanization Prospects. New York.
[4] USAID, 2015
[5] World Bank, 2011 Water Supply and Sanitation in Kenya – Turning Finance into Services for 2015 and Beyond. Nairobi
[10] http://www.theafricareport.com/Horn-East/kenya-country-profile-2015-that-engine-just-keeps-rolling.html

Figure 1: Sustainable Development Goals

Kenya has met a few of the Millennium Development Goal (MDG) targets, including reduced child mortality, near universal primary school enrolment, and a narrowing of the gender gap in education. Interventions and increased spending on health and education are paying dividends. Devolved healthcare and free maternal healthcare at all public health facilities is expected to improve health outcomes and develop a more equitable health system.

Speaking to the UN Assembly, Kenyan President Uhuru Kenyatta reiterated the country's commitment to the realisation of the Sustainable Development Goals (SDGs), indicating that the goals are not only ambitious, but will require immense resources for their realisation.

Transportation and Logistics in Kenya

Transportation infrastructure in Kenya remains relatively poor. Historically, Kenyan trade and national logistics developed from the port of Mombasa taking advantage of the Ugandan railroad. This linear spatial structure along a corridor, so common in sub-Saharan Africa, remains even after road traffic took over the rail and the more recent development of aerial alternative to the corridor. Currently, about ten million tonnes move along the corridor by truck, railroad or the Kenyan pipeline.[11]

The World Bank identifies two major challenges, among others, for the Kenyan freight sector:

- *The collapse of Kenyan Railways since the 1980s.* The Kenyan Railways Corporation has essentially left the freight market to the road sector.
- *Road infrastructure and its maintenance.* Kenya has an extensive network of predominantly unpaved roads (93%)[12] which have mostly been neglected for the past two decades. Reliable, paved roads are mostly restricted to urban areas where there is the most economic activity. The condition of some sections of the main corridor is very bad and is a serious bottleneck to the relatively high traffic (600 trucks/day from Mombasa).[13]

Kenya suffers from very high inland transportation costs, especially in rural areas. Notwithstanding the problem of rural poverty and the potential of trade to reduce poverty, existing logistics are not major constraints either for long distance transport or for the transportation of goods from the farm to processing plants or collection centres. Rural accessibility has been targeted by consistent policies, such as the Road 2000 programmes for minor roads.

[11] World Bank, Kenya: Issues in Trade Logistics, 2005
[12] Kenya Roads Board, 2015 Annual Public Roads Programme for the Financial Year 2015/2016. Nairobi
[13] ibid.

International and long distance logistics have been thriving in Kenya due to early deregulation, partly compensating for the decaying public services especially concerning rail transport. The private sector has been a key player in instigating and pushing the modernization agenda. These investments have improved the quality of services and operating costs of top providers in the trucking industry closer to European standards.[14]

Development Challenges

Kenya has the potential to be one of Africa's great success stories with a growing, youthful population, a dynamic private sector, a new constitution, and a pivotal role in East Africa. Addressing the challenges of poverty, inequality, governance, low investment, and low business productivity to achieve rapid, sustained growth rates will be a major goal for the country.

Kenya 2030 Vision[15]

The Kenyan Government has developed a 2030 vision focusing on the following 3 key pillars,

1. **Economic** pillar - improving the financial prosperity of all regions and all people in Kenya by achieving a 10% GDP growth rate by 2017. Six priority sectors that make up the larger part of Kenya's GDP and provide for nearly half of the country's formal employment were targeted, tourism; agriculture, livestock and fisheries; wholesale and retail trade manufacturing; IT-enabled services; financial services; and oil and gas.

2. **Social** pillar - investing in the Kenyan people in order to improve the quality of life for all by targeting education and training; health, environment, water and sanitation; population, urbanisation and housing; gender, youth and vulnerable groups; and sports, culture and arts.

3. **Political** pillar - moving into the future as one nation. This is anchored in the rule of law, democracy and improved public service delivery, transparency and accountability, public administration reforms and security, and peace building and conflict management. The sectors under this pillar include implementation of the constitution and legal reforms; leadership, ethics and integrity, national cohesion and integration; legal aid and awareness; strengthening the criminal justice system; and judicial transformation.

An area of potential interest for the reader may be the 2030 Vision objective to develop health and medical tourism in Kenya and improve access to specialized medical services, and to market Kenya as a destination for healthcare treatment in Sub-Saharan Africa. More details on this and other elements of the strategy can be found on their website http://www.vision2030.go.ke/

[14] [14] World Bank, Kenya: Issues in Trade Logistics, 2005
[15] http://www.vision2030.go.ke/

Kenya and the East African Community

Kenya is one of the founding Member States of the East African Community (EAC), and also has the largest economy of all the EAC countries.[16] The establishment of TradeMark East Africa (TMEA) in 2010 fostered the growth of both international and regional trade among EAC countries resulting in more efficient transport infrastructure, reduced transportation costs, and increased transport capacity. In 2008, after negotiations with the Southern Africa Development Community (SADC) and the Common Market for Eastern and Southern Africa (COMESA), 17 the EAC agreed to an expanded free trade area, including the Member States of all three organisations. The EAC is an integral part of the African Economic Community. Its economic growth has remained over 6% since 2006, which exceeds the global average. One of the advantages of the EAC is the harmonisation across countries, and in the area of healthcare this translates to harmonisation of regulatory processes. The EAC medicines assessors conducted their first joint dossiers assessment under the EAC Medicines Regulatory Harmonization Programme (EAC MRH) in October 2015, which will pave the way for reduced cost and easier access by all countries in the region. [18]

3. Health in Kenya

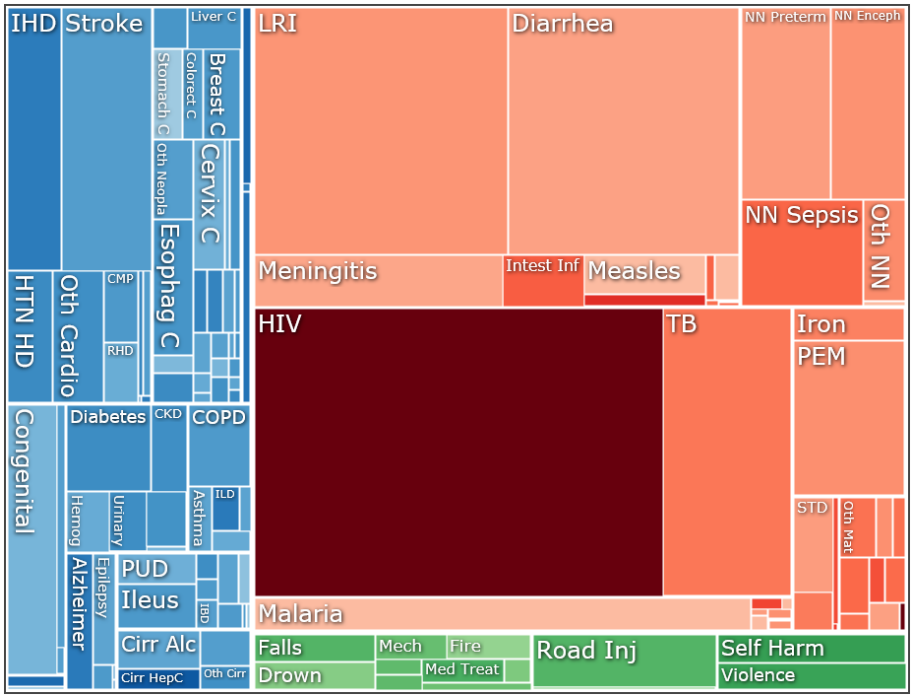
Kenya's healthcare system utilises monies from the national budget, private consumers, and donor contributions. The system is decentralised into four levels for ease of governance and responsibility: community, primary, county and national. 53% of healthcare costs are borne by the consumer when accessing services, making access to healthcare most difficult for the most rural and poor.[19] **According to the WHO, in 2010 half of all outpatient visits in Kenya occurred with a private healthcare provider, and 30% of all inpatient visits took place in a private healthcare facility.[20]**

National Disease Burden

Life expectancy at birth in Kenya was recorded at 62 years for males and 65 years for females in 2014.[23] According to the Institute of Health Metric Evaluation Data, records from 2013 show the main causes of death for all Kenyans to be HIV/AIDS followed by lower respiratory infection (LRIs), diarrhea, tuberculosis, and malaria (19.28%, 10.31%, 9.39%, 6.08% and 2.83%, respectively). HIV/AIDS, lower respiratory infect, and diarrheal diseases are also the greatest contributors to years of life lost (YLLs) as a result of premature death. Child and maternal malnutrition; unprotected sex; and unsafe water, sanitation, and hand washing contribute the greatest number of disability-adjusted life years (DALYs).

Figure 3: The main causes of death for all Kenyans

[16] The East African Community consists of the Member States Burundi, Kenya, Rwanda, Tanzania, Uganda and more recently South Sudan.
[17] https://en.wikipedia.org/wiki/East_African_Community
[18] http://mrh.eac.int
[19] German Foundation for World Population, 2011. Health Financing in Kenya. Nairobi
[20] World Health Organisation. Health services utilization and out-of-pocket expenditure at public and private facilities in low-income countries. 2010
[23] CIA World Factbook, 2014.



Source: Institute of Health Metrics Evaluation, Global Burden of Disease, Country Data, Kenya, 2013.

Healthcare Financing and Expenditure

According to the IMS Health African Insights Report, there are a diverse financing mechanisms for pharmaceuticals, including public financing through the Kenya Ministry of Health (KMOH) budget, subsidised user fees at public facilities, donor contributions, and direct private spending or indirect spending through insurance programmes. The WHO indicates that the majority of Kenyan healthcare funding comes from domestic sources (55%) and the remaining from abroad (45%). Spending by households remains the biggest source of expenditure on health followed by government expenditure.[25]

Table 1: Health Expenditure in Kenya (2013)[26]

Source	Proportion of Healthcare Expenditure	Value in USD (millions)
Government funded	42%	824
Social security funds (NHIF)	5%	108
Private funded	58%	1,150
Out of pocket expenditure	45%	881
External resources (Aid / NGOs)	6%	120
Private insurance	5%	107
Total	100%	1,974

There remains a considerable gap in the financing of pharmaceuticals. In public facilities, user fees are being used more and more to procure pharmaceuticals. Out-of-pocket and household expenditures

[25] Health System Financing Profile by country - http://apps.who.int/nha/database/Country_Profile/Index/en
[26] IMS Health African Insights Report Kenya

contribute notably to the total annual national expenditure on medicines.[28] Public financing (recurrent and development) estimates by WHO for 2011/12 was 1.9% of GDP and the public, per capita health spending was USD 19.20. In Kenya, funding for health research remains donor-driven, fragmented, and uncoordinated. Donor funding is the largest in all aspects of research, operations, and development, and approximately 99% of research conducted at the Kenya Medical Research Institute (KEMRI) is funded by development partners.

Diagnostics and treatment for many of the major diseases are co-funded by global agencies, such as Global Fund to fight AIDs, Tuberculosis and Malaria (GFATM), a performance-based financing mechanism. It relies upon countries to establish multi-sectoral partnerships (Country Coordinating Mechanisms, CCM) comprising state and non-state actors to seek, oversee, and harmonise its grants with national programmes. In Kenya, the CCM was formed in 2002, operating under the Joint Inter-Agency Coordination Committee supported by the Inter-Agency Coordinating Committees for HIV & AIDs, Tuberculosis and Malaria.[29]

HIV/AIDS: The number of patients receiving – and consequently the demand for – anti-retroviral therapy (ART) has increased substantially in recent years. Funding for HIV programming and treatment is received from the Government of Kenya (17%), GFATM (70%) and United States Agency for International Development (USAID) (13%).

Malaria: Total funding for malaria control in Kenya was about USD 1.5 billion in 2015 with roughly 10% funded by the Kenyan government, 30% from GFATM, and 33% by the United States Government President's Malaria Initiative (PMI).

Tuberculosis: The Global Plan for WHO's Stop TB Programme estimated the requirement for Kenya's TB Programme at USD 37 million in 2009. Of this, about 6%, or only USD 2.2 million, was budgeted for the purchase of first-line treatment. The Government of Kenya was to provide 21% of the required funding and GFATM also contributed, however, there was still a funding gap of 40%.

Health Insurance

The National Hospital Insurance Fund (NHIF) is a state insurance provider with a mandate to provide affordable quality health insurance to Kenyans over the age of 18 with a monthly income of KES 1,000 or more.[31] The following services are provided in hospitals under the NHIF Package, consultation, laboratory tests, drugs administration and dispensing, dental services, radiology, nursing and midwifery services, surgery, radiotherapy, and physiotherapy services.[32] These healthcare services provided by government

[28] Kenya health assessment system 2010 - http://www.cmamforum.org/Pool/Resources/Kenya-HSA-Report-Final-2010.pdf
[29] GFATM Kenya Five Year Strategic Plan 2015-2020
[31] www.nhif.or.ke/healthinsurance/index.php?option=com_content&view=article&id=70&Itemid=149&tmpl=component&print=1&layout=default&page=&option=com_content
[32] National Hospital Insurance Fund Benefits Package, November 2015.

hospitals is generally extremely cheap for patients without NHIF coverage, although of questionable quality, according to the doctors interviewed by IMS Health.

Private health insurance cannot be purchased without NHIF membership. Companies that offer employees healthcare coverage plans are likely to be in the formal sector where coverage is already very high (98%). Coverage within the informal sector, which accounts for over 80% of Kenya's workforce, remains low at 16%.[33] Using this information, IMS Health deduced that the population with NHIF coverage encompasses the entire health insurance market, but that a proportion does increase their coverage with the addition of a private scheme. The remainder of the population must pay for healthcare out-of-pocket.

An alternative option for those unable to afford private healthcare or out-of-pocket payments, who reject the highly variable care of the public sector, lies in the faith-based sector, which is extremely popular though not distributed evenly throughout Kenya. Furthermore, there are also donor and other smaller NGO programmes that provide vaccinations; maternity and neonatal care; and HIV/AIDS, malaria, tuberculosis and family planning service free or for little cost.

Table 2: Kenya's Top 10 Private Insurance Firms in Kenya and their Market Share of Health Insurance (2014)

Private Insurance Firms	Market Share
Jubilee Insurance	20.6%
AAR Insurance	13.7%
CIC Insurance	12.1%
UAP Insurance	11.6%
Resolution Insurance	9.6%
APA Insurance	9.3%
Heritage Insurance	4.9%
British American Insurance	4.4%
First Assurance	3.5%
GA Insurance	3.4%
Other - 10 firms	7.0%

According to the 2013 Kenya Household Health Expenditure and Utilisation Survey, about one in five Kenyans (17.1%) had some form of health insurance coverage. This shows an improvement from 9.7% and 10% coverage in 2003 and 2007, respectively. The NHIF covered 88.4% of those insured, and 9.4% had additional private insurance coverage. Community-based and other forms of insurance coverage covered 1.3% and 1.0%, respectively. Insurance coverage is higher among urban populations (26.6%) compared to rural populations (12.1%). NHIF coverage dominated in both rural and urban areas at 92.2% and 85.2% of those insured, respectively. Private insurance covered just over 4% among those living in rural areas and nearly 14% among urban residents. Unsurprisingly, health insurance was associated with

[33] IMS Health African Insights Report 2015

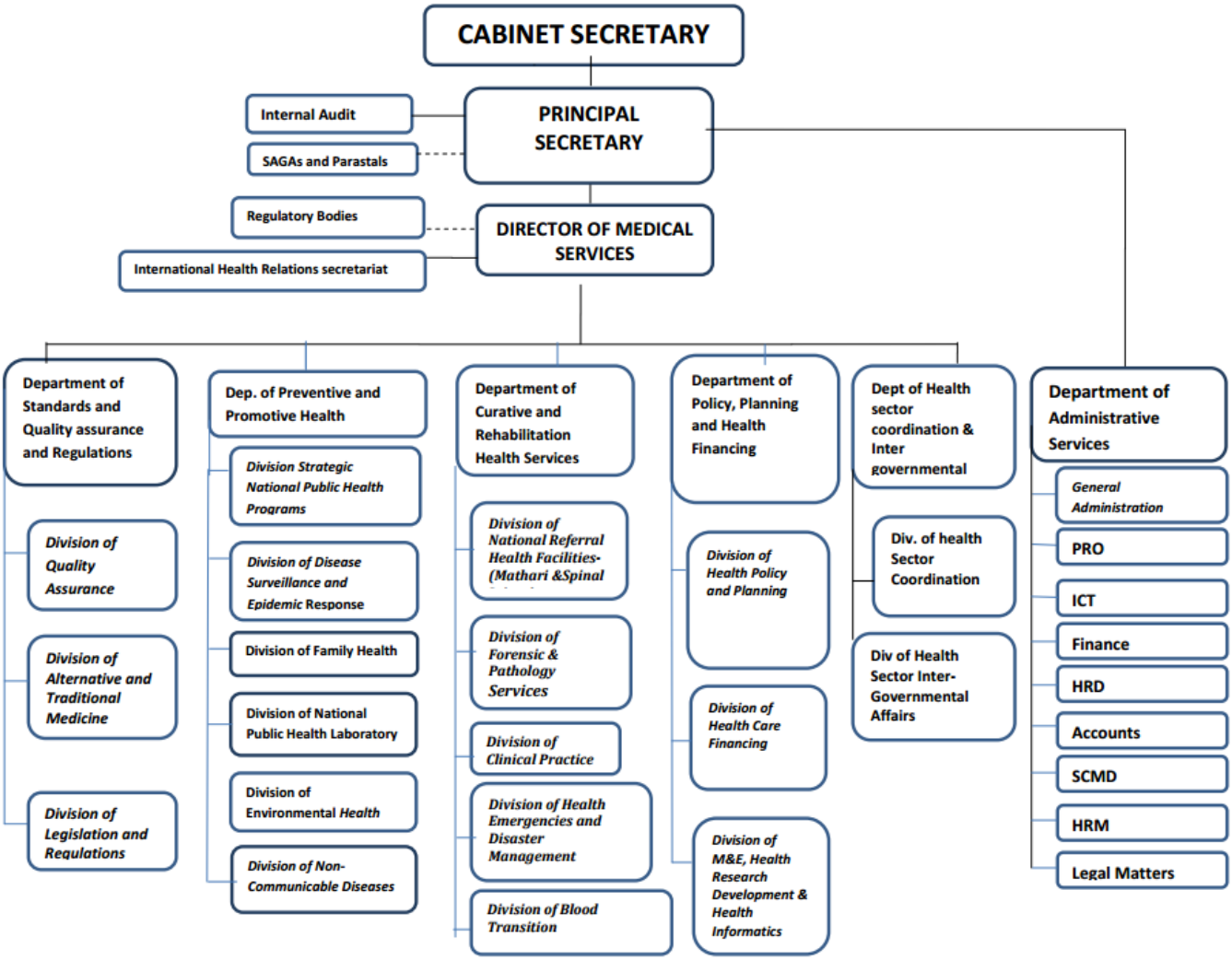
wealth status. The population in the richest wealth quintile reported higher coverage (41.5%) compared to those in the poorest quintile (2.9%).[35]

A breakdown of the costs of African health insurance schemes showed that that about 40% of total funds spent by insurers (USD 113 million) was on pharmaceuticals, the rest was for inpatient and outpatient care, medical devices, tests, and administrative costs.[36] Speaking with local pharmacists at upmarket pharmacies, they indicated that 100% of medicines were paid for in cash, not with insurance, which indicates that insurance claims must be filled for reimbursement. In spite of this, more and more people are investing in health insurance schemes and the demand for medicines is expected to rise.

[35] IMS Health African Insights Report 2015
[36] ibid.

Kenyan Ministry of Health Structure

The Kenyan Ministry of Health (KMOH), led by Dr Cleopa Mailu, manages an overall budget of KES 47.362 billion (USD 468.16 million) annually. The organisational structure is outlined in Figure 4 below with a mandate for health policy, regulation, national referral health facilities, capacity building and provision of technical assistance to counties. The KMOH has developed the Health Sector Strategic and Investment Plan (KHSSPI) outlining their strategy from 2013 to 2017.[37]



The KMOH operates approximately 50% of all health facilities in Kenya. These facilities receive their medical supplies from the Kenya Medical Supplies Authority (KEMSA). KEMSA-provided, public sector supplies account for 30% of all prescription medicines in the Kenyan market, whereas the faith-based organisation Mission for Essential Drugs and Supplies (MEDS) provides 45%.

[37] http://www.who.int/pmnch/media/events/2013/kenya_hssp.pdf

4. Medicines and Health Product Supply Chain

Pharmaceutical Supply Chain

The Kenya Medical Supplies Authority

Image from a KEMSA Warehouse

The GOK mainly procures medicines through the Kenya Medical Supplies Authority (KEMSA). KEMSA's purchases constitute an estimated 30% of all prescription medicines in the Kenyan market. The Authority also procures for some donor partners. **KEMSA is the sole public sector supplier of pharmaceuticals.** It procures pharmaceutical products directly through an open international tender (any local and international manufacturer and/or distributor is free to participate). KEMSA has a strong national distribution coverage serving over 4,000 public sector facilities, and it has recently experienced improved efficiency in coordinating the supply system. In addition, the governance and composition of the KEMSA board of directors recently changed to include representatives from the private sector providing an opportunity for strengthened collaboration between the two sectors.

KEMSA's supply system has traditionally followed a push model, where medicines and health products are delivered as part of an 'essential package' regardless of actual need. Inefficiencies in terms of stock management, such as over and undersupply resulted. Recently KEMSA began employing a pull model, where deliveries are based on demand, in most regions. As the established sole supplier for the entire public sector, KEMSA possesses an uncontested and solid capacity for nationwide storage of medicines and health products, with three national depots and warehouses (two in Nairobi and one in Mombasa), and six regional depots in Kisumu, Nyeri, Nakuru, Garissa, Nakuru, and Kakamega. KEMSA's nine regional depots are used primarily as bulk storage and sub-distributions points. From these depots, deliveries are made directly to public facilities at all levels nationwide.

To facilitate the transportation of medical supplies, KEMSA outsources courier services to the private sector. All supplies are delivered by road at no cost to health facilities. In partnership with experienced third-party transport service providers, KEMSA has set up a distribution structure with the capacity to reach all public hospitals, rural health centres, and dispensaries throughout the country.

A process has begun to integrate parallel programmes, such as reproductive health commodities, TB/Leprosy and ARV's into KEMSA's overall distribution process. Ultimately, this will cut down on distribution costs and ensure medical commodities are managed within one supply chain resulting in greater reach and efficiency whilst better utilising limited available resources.[38]

[38] http://kemsa.co.ke/index.php?option=com_content&view=article&id=6&Itemid=7

While transportation service providers are readily available, the quality of their vehicles and the services provided are not typically to the level of standards seen in developed countries. With the entrance of large multinational companies such as Pfizer and GlaxoSmithKline into the market, the demand for improved standards is slowly increasing.

Although KEMSA has adequate capacity to distribute to facilities nationwide, their distribution network is only as extensive as the network of public health facilities they can deliver to. The 'last mile' to the population includes what the national public health system classifies as 'Level 1' or the community level. At this level of healthcare medicines are largely covered by small, mostly unlicensed retailers.

Mission for Essential Drugs and Supplies

In addition to KEMSA, the Mission for Essential Drugs and Supplies (MEDS) is another large-scale, bulk procurer of medicines and health products.[39] MEDS was officially founded in 1986 to provide reliable, quality, affordable essential medicines and medical supplies to church health units and to train health workers on the rational use of medical resources. The organisation has since grown to shape the medical supply chain in Kenya and the wider sub-Saharan region by not only providing to over 1,820 health facilities but also to offer capacity building programmes for health workers, quality control, and other pharmaceutical services. It is the first faith-based organisation globally to be pre-qualified by WHO to analyse pharmaceutical products. About 45% of MEDS' annual turnover of about USD 12 million is spent on medicines and health products.

Laboratory and Diagnostic Supply Chains

The diagnostics supply chain in Kenya is dominated by USAID in the public sector and together with the Centre for Disease Control (CDC) are supporting efforts for HIV. KEMSA has recently started to procure some diagnostics, though the private sector tends to be the main supplier of diagnostics services and is dominated by distributors who tend to be Original Equipment Manufacturer (OEM) specific. The KMOH is currently upgrading 98 facilities across the country under a managed equipment services arrangement that brings together OEM and the Government. All the major OEMs have shown great interest.

Marginalised populations mainly access diagnostic services through the public sector and faith-based enterprises. Confidence in the public sector is increasing but still skeptical. Large infrastructure investments have improved facilities, but staffing shortages and lack of motivation as well as financing gaps present challenges. Following the implementation of the Managed Equipment Services programme (MES) to improve public facilities, the public sector is expected to compete favorably with the private sector except on specialised tests. For example, Turkana County has invested in the bio chemistry and hematology analysis machine, GeneXpert, and can now perform up to 700 tests per day and will be fully accredited later this year; this will be the third public health lab to be accredited in Kenya.

[39] http://meds.or.ke/index.php/about/our-history

The major stakeholders in providing laboratory services are varied and include laboratory groups, such as Lancet Pathologists and Pathcare from South Africa are in Kenya, as well as Medanta from India. Distributors tend to be manufacturer-specific. Major distributors are Crown Kenya, Sciencescope, Phillips, and Chemoquip. Many products are being imported from India and China and routed directly to the labs without going through wholesalers as most of the systems tend to be closed. Retail pharmacies are now providing some testing, mainly pregnancy, malaria and blood sugar. Equipment manufacturers include Abbott, Roche Diagnostics, Human, and Siemens.

The regulating body is the Kenya Medical Laboratory Technologists and Technicians Board (KMLTTB). They have clear guidelines in registration and importation and there is a requirement for validation of some equipment and tests that adds to cost and delivery time.

Quality assurance is one of the biggest challenges. Some studies estimate that 30% of medicines in Kenya are counterfeit, mainly due to unregulated or poorly regulated parallel import systems. One of the main issues in diagnostics is validation and accreditation of laboratories. Strengthening the regulatory bodies will go a long way to improve diagnostic quality. Automation of licensing and permit processes is well underway.

There are also gaps in national guidelines for disease management and this leads to the use of high cost products and procedures without necessarily an impact on care and patient outcomes.

Devolution

Devolution has greatly clouded the diagnostics landscape in Kenya. Much of procurement is done at the county level, though KEMSA remains a key player. Since devolution began in 2010, there have been many cases of doctors and nurses going on strike due to lack of or late payment, lack of job promotions, and so on. Turkana County, however, is an exception. For years this county had the lowest health indicators, and when decentralised government was instituted, it made a deliberate decision to commit the biggest share of its budget to the health sector.[42] The result is a revamped sector with well-equipped health facilities and improved service delivery to the people.

Supply Chains in the Private Sector

Kenya dominates the regional pharmaceutical market with over 50% of medicines manufacturers in COMESA with operations there. Despite that, Kenya remains a net importer of pharmaceuticals, largely from India and China.

The private pharmaceutical distribution system in Kenya has clear structures, is well-established, organised and demand-driven. Due to low purchasing power, the majority (63%) of Kenya's pharmaceutical market is comprised of generic medicines (including branded products whose patents

[42] https://www.youtube.com/watch?v=0kBVITA_ebY)

have expired).[44] Furthermore, as a result of high levels of poverty, self-medication is very prevalent in the country; this raises the prospects for the over-the-counter (OTC) market (28%).

According to Business Monitor International (BMI), Kenya's pharmaceutical market was valued at KES 55.29 billion (USD 642 million) in 2013. In that same year, per capita drug expenditure was just USD 14, which is extremely low on a global scale. Pharmaceutical expenditure took up 1.5% of GDP and was below the global average. Nevertheless, in comparison with many other African markets, Kenya offers more commercial promise and a more stable business environment.
Patented drugs account for a small market share of medicines as low per capita expenditure continues to limit the capacity of most of the population to purchase the higher-priced products. Patented drugs accounted for 9% of the total pharmaceutical market at a value of KES 4.96 billion (USD 58 million) in 2013.

Pharmaceutical distribution remains highly fragmented with a large number of suppliers, each dominating a specific geographic region or range of commodities.[45] There are over 30 large distributors in Kenya, most acting as agents for international manufacturers. Distributors serve an even larger number of wholesalers, mostly operating from the major cities. Distribution capacity tends to be relatively poor, particularly in rural areas. And with mark ups being added at each level in the supply chain, high prices and uncertain quality to pharmacy retailers are the natural consequences of this fragmentation. It also makes it very difficult for insurers to offer pharmacy benefits.

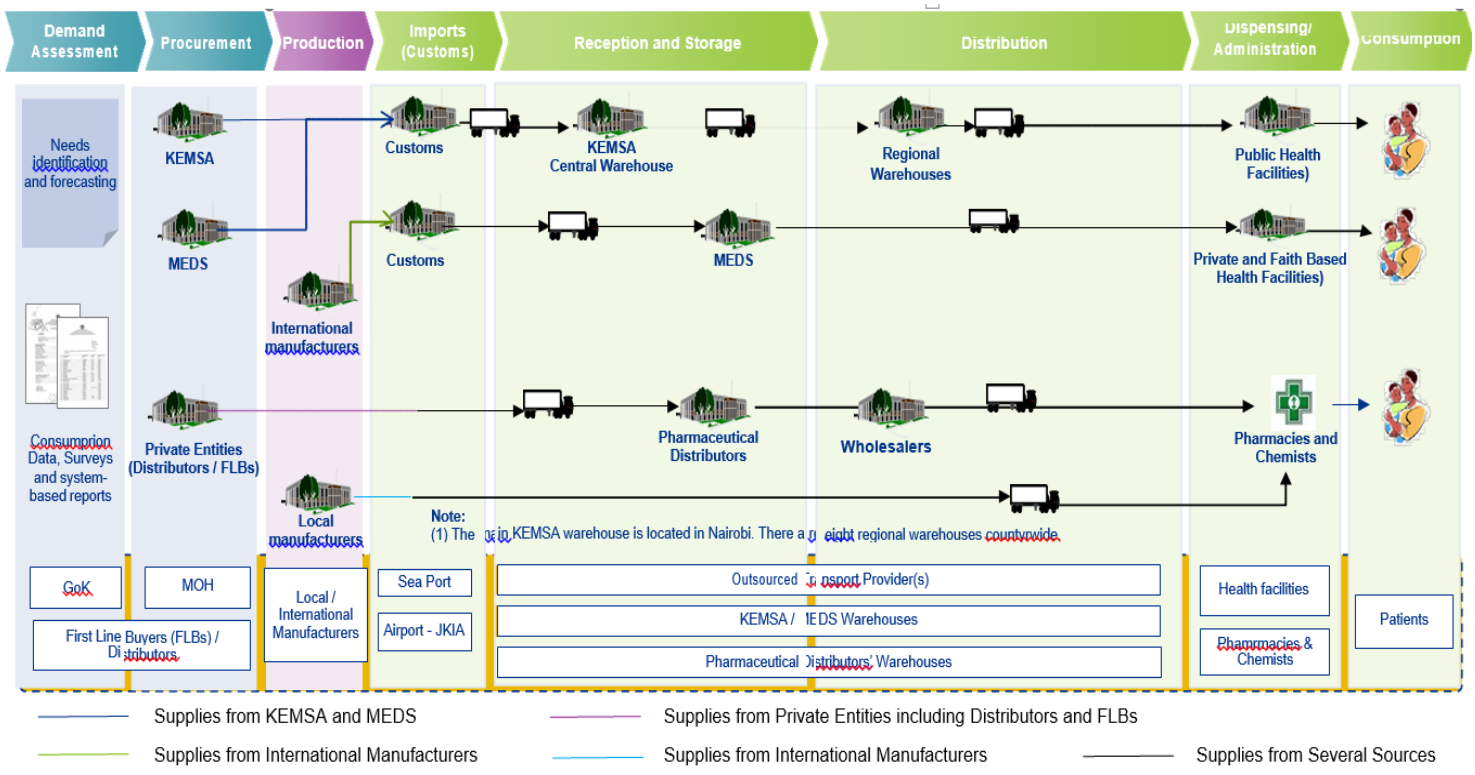
The retail pharmacy market has a proliferation of poorly regulated small pharmacies,[46] many of which would appear to be barely solvent. It is estimated that there are more than 6,000 pharmacies in Kenya, mostly in urban and more affluent areas. However, approximately 1,031 of these pharmacies are registered with the Kenyan Pharmacy and Poisons Board (PPB) leaving a large number operating without proper registration and licenses attended by unqualified staff. The scale and variance in the market make it difficult for the under-resourced regulators to enforce laws and for consumers to distinguish quality services, especially in rural and low-income areas. For example, Nakuru and Mombasa have the largest number of registered pharmacies outside of Nairobi, but also have many unregistered outlets, which are operated by unqualified staff and sell expired and substandard products, including antibiotics and analgesics. Although the PPB is taking action to stem out illegal outlets it is a difficult task. Fragmentation creates a number of problems for retailers and consumers. However, it potentially creates an opportunity for consolidation through a centrally controlled chain.

[44] Imperial Health Sciences, African Investors Trip, 2014.
[45] Imperial Health Sciences: The rapid assessment found that four suppliers (Transwide, Transchem, Nila and Njimia) controlled over 80% of the supply to retail pharmacies in Nairobi, but had negligible share in the Western region. Similarly, the major suppliers in the Western region had no market share in Nairobi.
[46] Imperial Health Science: Of those pharmacies studied, nearly two-thirds had only one or two staff. The average size of the premises was 35m^2, with most consisting of a single room where prescription and general sale of medicines are combined; this is not permitted by law. A past study found that over four-fifths of pharmacies did not have a separate dispensing area, a basic licensing requirement.

Local and Multi-national Pharmaceutical Firms in Kenya	
Local manufacturers	Cosmos, DAWA, Regal, Universal, Betacare, Sphinks, Njimia
Top multi-nationals in Kenya (by market size)*	GSK (UK), Pfizer (US), Novartis (Switzerland), Sanofi-Aventis (France), Roche (Switzerland), Bayer (Germany), Adcock (South Africa), Astra Zeneca (UK), Jansen (Belgium), MSD (UK), Abbot (US)
Local distributors that deal with generics	Glenmark, Laborex (Kenya), Philips, Sunpar (Kenya), Sun, Europa, Harleys, Galaxy, Medox, Lords, Surgilinks, Surgipharm, PSM, Betacare, Njimia, Denk, Pan, Simba, Ranbaxy
Top multi-nationals dealing with generics in Kenya (by size)	GSK (deals with branded and generics), Glenmark, Sun, Ranbaxy, Medser, Laborex, Surgilinks, Philips, Cipla
Pharmaceutical Distribution Market (First Line Buyers)	
Laborex Limited, Surgipharm Limited, Harleys Limited, Phillips Pharmaceuticals, Lords Healthcare, High Chem Pharmaceuticals Limited, Sai Pharmaceuticals	

5. The Healthcare Value Chain

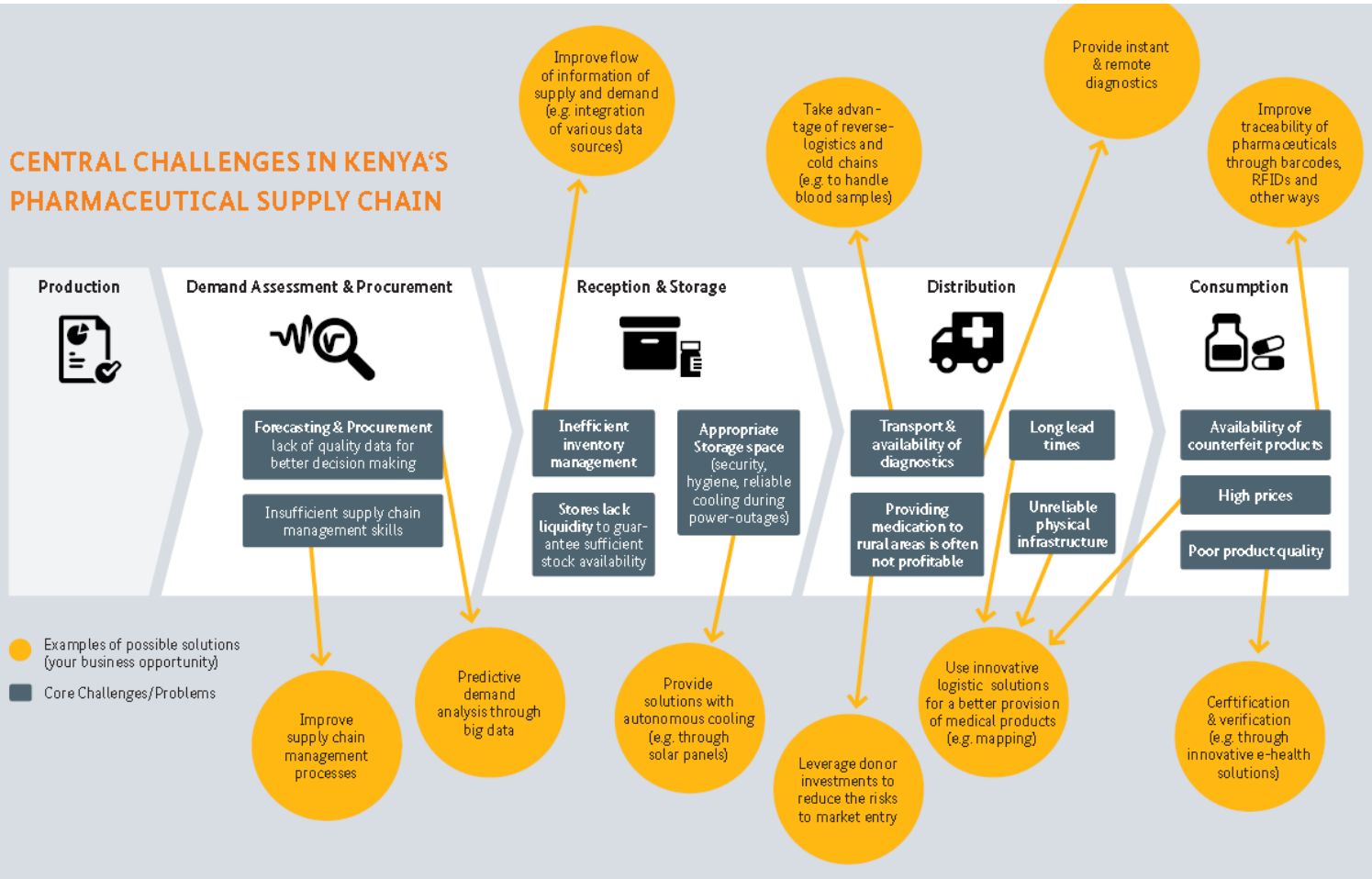
Below is an overview of the healthcare value chain for both public and private markets in Kenya.



- All medicines in the distribution chain must be registered by the PPB and should meet quality requirements as set by the Kenya Bureau of Standards (KEBS). Each manufacturer is responsible for the quality of its medicines in the distribution chain. The manufacturers, together with the distributors, are responsible for the mode of distribution, pricing, and promotion. In many cases, they employ medical representatives who provide detailed information on the products to prescribers, medical institutions, pharmacies and other medical workers. Pharmacists and more experienced medical representatives also provide continuing education seminars. Most up-market hospitals prefer to receive product information through such seminars, whereas others prefer to get information in one-on-one sessions with medical representatives.

6. Challenges along the Value Chain

Accessibility, availability, affordability and quality are critical to improving health outcomes and are significantly impacted by the supply chain.



Public Healthcare Challenges

Challenges observed in the public health system occur along the supply chain and are highlighted below (details are outlined in Annex A).

The underdeveloped state of Kenya's rural healthcare infrastructure places significant limits on access to medicines and health products for Kenya's rural populations. The problem of access is compounded by a shortage of essential drugs in rural areas, due to an inefficient supply chain and understaffing in public health centres. Furthermore, a young population (42% under age 15) and short life expectancy make for a low non-communicable chronic disease burden thus limiting the overall demand for chronic disease treatment. Despite this, strong population growth and urbanisation should support market growth.

According to BMI, poverty continues to limit the participation of many people in the pharmaceutical market and encourages the prevalence of counterfeit drugs. Kenya's overall pharmaceutical export to Tanzania, Uganda, Sudan, and Somalia has increased tremendously over the years at 18% compound annual growth rate.[47] In 2008, almost 50% of these exports went to the neighboring East African Community (EAC) countries of Tanzania and Uganda; exports to Sudan accounted for about 14%.

Private Healthcare Market Challenges

The private healthcare market cannot be ignored and is essential to ensuring access to medicines and health products for all. However, investment in the private healthcare market has been limited when compared to the investments in the public health system. Building a commercially viable pharmacy chain in an emerging market is inherently complex and risky, especially when targeting low income populations.

Some of the biggest challenges from the private sector standpoint are: the high consumer prices due to the multiple tiers and their mark ups in the supply chain; the availability of quality distributors and wholesalers that have access to capital as well as sufficient reach to those populations in the most remote areas; poor quality and counterfeit medicines in the system, and lack of consumer awareness.

7. Tackling Challenges and Solutions to Explore

Availability

Stock-outs are experienced on an ongoing basis in Kenya as a result of limited consumption data, low awareness , long replenishment lead-times and availability of funds. Stock-outs in diagnostics can be quite high given the short shelf life of the reagents and variable demand. From a beneficiary standpoint, if a commodity is not available this can result in a diagnosis not being completed, a patient being provided a treatment that may not be as effective, requiring referral or approaching the private sector which will entail out-of-pocket payments, or going without treatment entirely. In the private sector we also see other drugs recommended that may be of poor quality or are counterfeit.

In 2013, approximately 48% of 87 public health facilities across 5 districts in Kenya were experiencing stock-outs of one or more anti-malarial treatments, and nationally stock-outs were 51%. With the introduction of 'SMS for Life' a text messaging solution across the 5 districts, a 38% decline in stock-outs was seen over a 26-week period.[48]

There is still a lot of work to be done on building awareness around the most appropriate treatments for a specific disease presentation, e.g. oral rehydration salts and zinc when a child presents with diarrhea. While there are improvements in reducing lead-times, the funding flows and disbursements for the public sector at a county level need to be improved and ensuring availability of all essential medicines is critical.

[47] The year-over-year growth rate of an investment over a specified period of time.

[48] Githinji et al. 2013. Reducing Stock-Outs of Life Saving Malaria Commodities Using Mobile Phone Text-Messaging: *SMS for Life* Study in Kenya. *PLoS One*. 2013; 8(1). Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3547931/

Affordability

While price negotiations by major international organisations, such as GFATM, USAID, UNICEF or CHAI have had a huge impact on price reductions in the public sector, pricing in the private sector value chain remains high. This is driven by the cost of moving commodities through the value chain and the mark-ups added along the value chain to compensate for the financial risks the various players take.

In recent years, Merck Sorono prepositioned its inventory in Kenya at the Imperial Regional Distribution Center. They moved from an exclusive distributor to engaging 2-3 local distributors and therein reduced the end price to the consumer by 20-30%, which tripled their business and that of their distributors.

Some risks borne by the importer and distributors including the cost of capital, working capital etc. can be reduced by the manufacturers making their commodities available in country and extending capital not only to the distributor but also to wholesalers and retail pharmacies. There are also opportunities to improve the procurement of medicines and health products across different organisations, such as hospitals and retail pharmacies, by utilising a pooled/group procurement model, [49] or a direct-to-patient model, [50] which is being used in South Africa for chronic medicines.

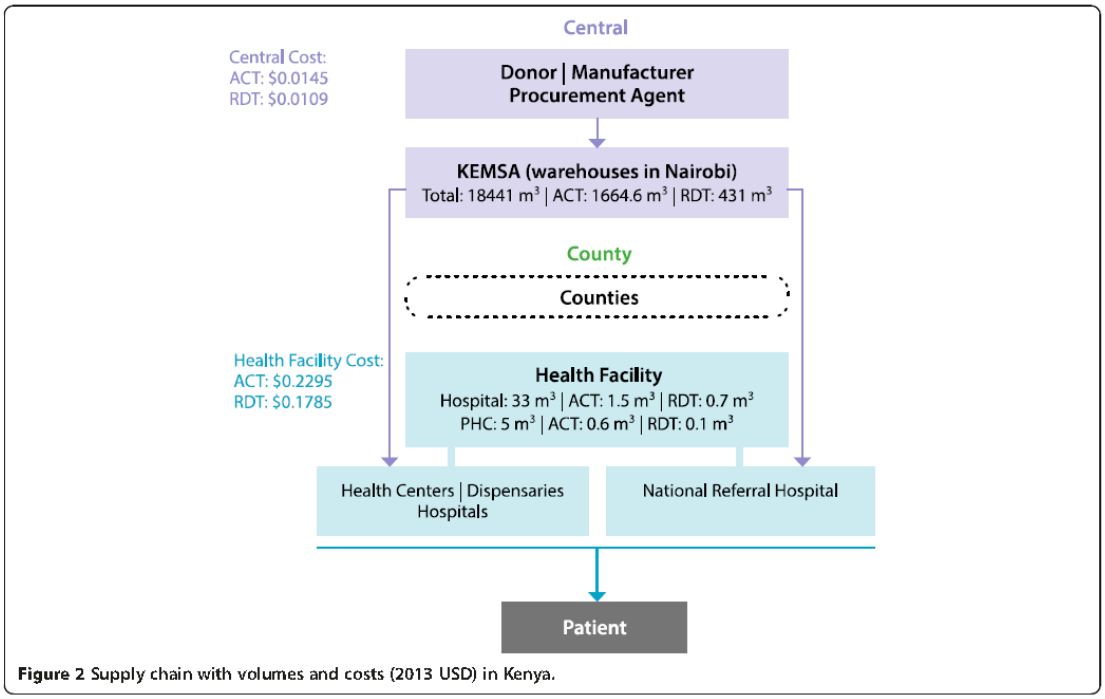


Figure 2 Supply chain with volumes and costs (2013 USD) in Kenya.

[49] Pooled procurement describes group activities to improve the outcomes of procurement for individual members. When implemented successfully, such mechanisms can help countries access a sustainable supply of quality vaccines, achieve greater demand predictability, reduce transaction costs and the total price paid for vaccines and related products (WHO, 2016).

[50] Direct-to-patient distribution is a mechanism whereby products are delivered directly to the patient. This is useful for patients with regular prescriptions or chronic disorders and it can have positive effects on ensuring a temperature controlled supply chain (www.marken.com).

Visibility

Accurate consumption data or point-of-sale data is difficult to acquire due to the manual processes currently used for data collection and the fact that the health workers responsible for reporting data are often overworked.

Vaccines require temperature-controlled environments to be stored and distributed, however, there are many instances where the appropriate temperatures are not maintained, affecting the quality of the vaccines . The application of barcoding, radio frequency identification or mobile technologies, along with temperature monitoring sensors, is becoming more commonplace for the collection and monitoring of medicines and health products. Awareness around control towers and how they can be used for analysing and using data appropriately, is slowly evolving.

Quality

Many challenges related to poor quality and counterfeit medicines exist, especially at unregistered facilities. While the PPB is looking to address this issue, there is still a long way to go. Poor storage and transportation conditions also lend itself to the quality of the medicines deteriorating over time.

International organisations have entered the Kenyan market and engaged local, third-party logistics providers to provide storage and transportation services, working with them to improve their standards so that they meet international standards for pharmaceutical grade/compliant storage and distribution expected by multinational companies. Insufficient attention has been given to cold chains and specifically to the maintenance of the temperature-controlled environments.

The Way Forward

The complexity and number of stakeholders involved in providing healthcare in Kenya lend to the challenges, but also provide opportunities to address them. This can include leveraging private sector expertise in both the public and private sector, introducing finance mechanisms and access to capital that encourage and enable market development and growth, shaping the market to address market failures, and increasing availability, quality, and analysis of data to improve decision making.

These innovations and more will be further explored at the lab of tomorrow workshop on 17-19 May 2016.The following examples provide example solutions to inspire and inform further discussion and innovation at the lab.

Example Solution: Development of Retail Pharmacy Chains

Considering the overall challenge of availability and affordability of quality medicines and health products, a holistic approach can be taken that will build the capacity of the various stakeholders in the value chain. Extending reach to low income families can be achieved at scale through a concept, such as developing retail pharmacy chains. Fundamental to success, to minimising both risks and cost, is that the skills and experience necessary for establishing and running a pharmacy chain be available in the market

and fully utilised wherever possible. Should it be necessary to develop core skills and expertise in organisations without previous experience in the area there would be an increased risk of failure.

The array of experience required covers a wide range of areas:

- Ownership and management of clinics serving the target population
- Managing a clinic franchise network of sufficient size to provide an adequate backbone for establishing a pharmacy chain
- Management of a retail chain
- Purchasing and supply management and operations able to offer:
    - Nationwide distribution
    - International and national sourcing and buy-ins
    - Stock integrity and management
    - Stock availability
    - Buying and pricing power
    - Short lead times
    - Traceability
    - Reverse logistics
    - Validated cold chain

Given the complexity of such an initiative, it is also important to minimise the number of partners involved.

In this context, the following criteria were considered essential to guide the identification and selection of companies and organisations best suited to build a successful pharmacy chain in Kenya:

- An established presence in the Kenyan market that was already operating at scale or building a presence that is expected to achieve scale within the foreseeable future
- Demonstrable expertise in their field of operation
- Serving low and middle income populations
- A commercial approach to providing services

Example Solution: Serialisation

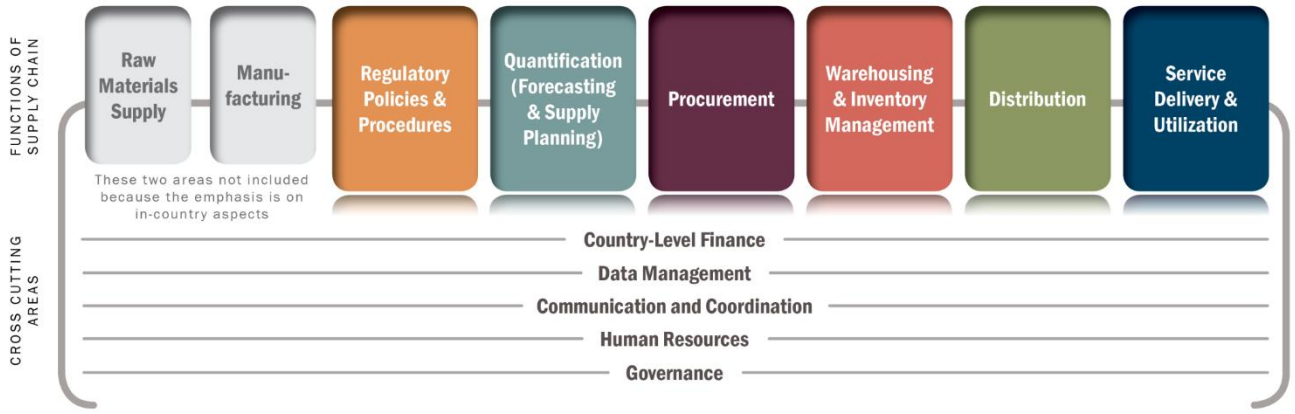
In looking to address challenges around visibility and quality, there is an opportunity to explore a ‘serialisation’ initiative learning from the examples in USA (Pedigree), Europe, and Turkey to be able to track and authenticate commodities to the retail or patient level. This data will also be extremely valuable in managing supply chain activities, including better understanding consumption/demand, as well as enabling improved replenishment.

8. Annexes

Annex A: Functions of the Supply Chain and Key Barriers

UN Commission on Life-Saving Commodities (UNCoLSC)
Recommendation 6, Outcome 1: Good Practice in Supply Chain Management
Challenges and Barriers along the In-Country Supply Chain

To increase access to life-saving commodities for women and children, barriers to improving in-country public supply chains must be understood. The purpose of this document is to summarize barriers related to the supply chain to provide a framework from which to create a best practices review. This document expounds on barriers identified by the UN Commission on Life-Saving Commodities for Women and Children Commissioners' Report, September 2012, and also draws from additional resources, to summarize the key barriers that need to be addressed to ensure good in-country practices in supply chain management. These barriers are grouped into broad themes, while fully recognising that they are interrelated and interdependent. This document focuses only on aspects specific to in-country supply chains as other recommendation working groups are focused on other areas.



FUNCTIONS OF SUPPLY CHAIN

Regulatory Policies & Procedures

- Policies and systems (registration, quality control, drug authenticity verification, importation) that can potentially restrict product selection, delay shipments, or make entry prohibitive
- Omission from the National Essential Medicines List that can prevent procurement
- Weak quality control and assurance systems along the supply chain
- Limited quality control capacity that can delay testing and release of product into the system

- Limited enforcement of policies that do exist; limited capacity of regulatory bodies

Quantification (Forecasting & Supply Planning)

- Lack of mechanisms and tools for proper forecasting and supply planning
- Poor, inadequate, or inaccessible data that makes it difficult to forecast and plan commodity needs
- Lack of coordination between supply planning and technical units
- Lack of capacity for quantification
- Existing tools that do not take local context into account, and therefore cannot be applied properly
- Limited number of staff trained in proper quantification, forecasting, and supply planning processes
- Focus on public sector forecasting, rather than the whole market approach
- Lack of understanding of the difference between quantification for budgeting and quantification for supply planning

Procurement

- Poor collaborative planning between quantification and procurement
- Unpredictable and long lead times for delivery of procurements
- Bureaucratic and encumbered procurement processes
- Lack of coordination and/or standardisation of products to procure
- Lack of consideration of recommended case management products (e.g., pediatric dosages)
- Little use of procurement flexibilities (e.g., framework contracts)
- Insufficient use of master supply agreement with best price possible based on volume discount
- Lack of agreement between standard treatment guidelines and National Essential Medicines List
- Lack of knowledge and skills for procurement planning and tendering within the public sector
- Limited competition in the private sector, leading to a lack of technical expertise to support the public sector and potential conflicts of interest or corruption
- Inconsistent flow of funds
- Lack of communication between the public and private sectors on changes in policy, regimens, etc.
- Lack of flexibility in funding strategies

Warehousing & Inventory Management

- Stock leakage and security issues with low product traceability throughout the supply chain
- Inadequate storage space and conditions, complicated by cold chain requirements for some temperature-sensitive commodities and by infrequent distribution of large quantities to stores with limited storage capacity
- Disposal policies absent or not followed

- Poor adherence to inventory best practices—stock rotation (first-to-expire, first-out [FEFO]), batch control, stock recall processes
- Poor inventory management (i.e., routine cycle counting of stock, physical inventory and reconciliation)
- Duplication created by a lack of communication between public and private sectors
- Lack of capacity of those managing inventory
- Administrative, rather than functional, positioning of warehouses
- Very little knowledge of operational costs, cost of goods in public sector
- Low-skill levels for managing outsourced warehousing

Distribution

- Inconsistent availability, reliability, and quality of transport infrastructure and services, especially at the last mile
- Limited funds to support distribution costs at the lower administrative levels of the health system
- Excessive distance between health centres and resupply points and between community health workers and health centres
- Ad-hoc distribution strategies and poor distribution planning with limited incentives for timely distribution
- Seasonality, affecting the need for some commodities, and geography, with terrain being a challenge for transportation
- Maintenance of cold chain during distribution for temperature-sensitive and cold chain dependent commodities
- Poor data management and/or lack of sufficient stock at higher levels of distribution
- Limited engagement with private sector providers
- Lack of organisation and consolidation of private sector distributors; no incentives to consolidate and no synergy with public sector distribution networks
- Low quality of private sector distributors
- Limited capacity on government side to manage outsourced distribution contracts

Service Delivery & Utilisation

- Inadequate health personnel training and knowledge gaps at each level of distribution, leading to under utilisation or misuse of commodities
- Sub-optimal delivery mechanisms, product packaging, formulation, and distribution requirements lead to under utilisation or misuse of commodities and can complicate supply chain management
- Competing priorities for health personnel time
- Lack of commitment to timely and accurate data collection and/or reporting
- Limited supervision of supply chain management tasks at service delivery points (SDPs)

- Poor access to hard-to-reach communities
- Inadequate information provided to the community on service delivery and product availability issues, leading to low or nonexistent community engagement and limited accountability
- Poor conditions at health facilities
- Lack of coordination in donor assistance that supports supply chain and health services
- Limited monitoring of private sector SDPs (small shops, vendors, private providers)
- Lack of access to favorable pricing for private sector

CROSS-CUTTING AREAS

Country-Level Finance

- Budgetary constraints, particularly for key commodities and supply chain management
- Slow and inconsistent funding flows with inefficient use of funds
- Inadequate funds at the lower administrative levels responsible for distribution to rural primary health facilities
- Disparate, uncoordinated funding sources, and difficulties accessing budgeted funds
- Poor or incomplete understanding of supply chain costs with a tendency to under-budget
- Out-of-pocket expenditures for end users
- Ambiguous or amorphous business models within medical stores
- Reliance on donor funding which imposes distortions in supply chain management and in the market
- Lack of analysis and capacity to understand mechanisms to reduce both costs and price
- Lack of capacity building around budgeting and financing activities

Data Management

- Unclear protocols and inadequate training of staff for appropriate data collection and utilisation
- Outdated or non-existent information systems and record keeping
- Competing software for managing supply data at different levels of the health system
- Poor logistics data, such as inadequate dispensed-to-user data
- Little emphasis on performance measurement
- Delayed/inaccurate/incomplete reporting from SDPs and multiple levels up the reporting chain
- No open, easily accessible, shareable, and standardised data portal available to all partners
- Lack of two-way flow of information to and from the central level and SDPs
- Insufficient use of data for decision making at all levels for procurement, distribution, and monitoring
- Poor supervision of data quality
- Lack of access to private sector data to include in modeling, forecasting, and quantification (proprietary nature of data)

Communications & Coordination

- Lack of synergies from technical and financial partners; poor communication and coordination among partners
- Lack of staff adequately trained in procurement processes—inattention to procedures, process quality concerns, and timelines
- Suboptimal coordination efforts with regional entities
- Inadequate coordination between parastatals and government health programmes
- Financing and operation (including commodity provision and reporting) of public sector programmes stove-piped by disease category
- No formal mechanisms by which the public sector can engage the private sector
- Fragmented/disorganised private sector which limits the public sector's ability to engage

Human Resources

- Training gaps and limited capacity for quantification, procurement, product quality assurance, and stock management
- Few health personnel trained in the specifics of supply chain management
- Outdated or non-existent standard operating procedures with few user-friendly job aids
- Turnover and high mobility of personnel; limited number of healthcare providers and heavy workloads
- Low motivation to accomplish routine supply chain tasks such as reporting
- Lack of supportive supervision
- Lack of a systemic approach to human resources for supply chain
- High number of temporary and external staff involved in managing the supply chain
- No defined minimum standards for supply chain management positions, no professionalisation

Governance

- Lack of commitment from leadership at every level of the health system to improve supply chain management and to ensure these commodities are in stock
- Government distribution systems with limited ability or capability to create incentives for improved supply chain management
- Lack of national policy guidelines on utilisation of specific products
- Lack of metrics and understanding of the business and management aspects of supply chain performance (private sector invests in supply chain overhauls because it's good business)
- Lack of holistic planning and long-term planning
- Budget inefficiencies due to lack of an effective coordination mechanism for commodity decision making across products and programmes
- Lack of accountability on supply chain performance at all levels

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