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KENYA

Health Sector Constraints & Opportunities for Enhanced Growth

A policy paper

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This Policy Position Paper is made possible by the support of the American People through the United States Agency for International Development (USAID), through the Prosper Kenya Initiative Cooperative Agreement between USAID and AmCham Kenya. The contents of this paper are the sole responsibility of AmCham Kenya and do not necessarily reflect the views of USAID or the United States Government.

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Executive Summary

Executive Summary

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This policy position paper presents an analysis of key policy hurdles and positions in the Health Sector. These policy hurdles were identified in preceding policy scoping reports that involved in-depth desktop research, including a literature review of documentation from public sources, which informs key statistics in the report. An analysis of existing Health sector policies was carried out, highlighting priorities and current gaps, as well as an analysis of the commercial landscape, which underscores the sector's opportunities and risks. The results of the scoping/analysis were presented to Chamber members and other key stakeholders for validation and review. The policy positions presented in this paper have been developed as a result of both the research and consultation with AmCham members.

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Kenya ascribes to Health in All Policies (HiAP), an intersectoral approach that facilitates decision-making among policy-makers in order to maximise the positive health impacts of other public policies. The goal of this Kenya Health policy is 'attaining the highest possible standard of health in a manner responsive to the needs of the population.'

C

As the impact of Covid-19 continues to escalate, we have seen measures and funding in the health sector align to support the needs of people living in poverty and vulnerable populations. Though the approach to the UHC implementation process remains incremental, the new COVID-19 related governance structures have brought the health docket into the president's immediate purview, which could potentially create both a barrier to coordinated policy formulation and an opportunity to engage on healthcare issues within the highest levels of government.

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KEY POLICY HURDLES IN THE SECTOR INCLUDE:



Sectoral and structural challenges: There have been challenges regarding deep institutional restructuring and intergovernmental coordination.



Poor quality, management and availability of health data: Despite data management being enshrined in Kenya's eHealth Policy since 2011, the health ministry has been unable to get a clear picture of national operations, driving up mismanagement and corruption.



Lack of adequate human resource capacity in the public sector: The health workforce in the public sector has been characterised by critical shortages, uneven distribution, frequent industrial action and an inadequate skill mix.



Health financing: Kenya is grappling with rising healthcare costs and increased demand for healthcare services in the face of ongoing budget constraints.



National - County and subcounty dynamics: There is the lack of a clear legal framework for transferring resources and functions from the county level to sub-county levels, and, within the counties, the same lack of a framework for transferring resources between micro-units, such as wards. Additionally there have often been funding delays and budgetary allocation challenges between national and county governments.



Lack of alignment or harmonization between regulatory agencies: Due to the duplicity of roles played by regulatory agencies in the sector, a need for harmonized standards and procedures have been cited.



National Reimbursements System: Reimbursement level for life-saving treatments – i.e. there is need for sustainable reimbursement models that would improve market feasibility and allow for greater activity in the private sector, driving an increase in life-saving curative therapies (particularly important due to low-to-no grant funding provided for example cancer and noncommunicable diseases). National reimbursements systems are designed to pay for curative care, which disincentivizes providers from engaging in preventive and promotive care. This ends up being very costly on the health system. For instance, neither NHIF nor private insurance pays for contraceptive use.



Illicit and Counterfeit Trade: Trade in counterfeit and contraband goods remains a major problem for Kenya, despite a decade of unprecedented legal and institutional efforts to control it. COVID-19 has intensified the spotlight on the trade in health products. There has been a mushrooming of unregulated chemists, which are the major centers of trade for these illicit drugs, compounded by consumers to purchase the cheapest goods and services on offer.



Inadequate systems and incentives to grow the local manufacturing sector for the production of health products and technologies.

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Nevertheless, measures can be implemented to address these hurdles:

- **Public-private partnerships (PPPs):** Challenges such as financing in the healthcare system can be addressed through partnerships between the public and private sectors.
- **Public-private dialogue (PPDs):** Engagement between public and private sectors are key to ensuring a favourable environment for doing business.
- **Utilizing technology to enhance health service delivery:** Healthcare systems continue to undergo ongoing pressure to increase the quality and efficiency of care and find new ways to use data, systems and distributed networks of providers to provide quality health services.
- **Supporting capacity building for the health sector workforce:** Challenges in human resource capacity can be addressed by the development of a framework and national plan to grow the workforce.
- **Lobbying and advocacy to drive regulatory reforms to address policy lag, structural and sectoral challenges in the sector,** especially for the development of a comprehensive UHC framework and to ensure the success of NHIF reforms.
- **Development of an illicit trade index** which will provide evidence of pricing and actual illicit trade practices.

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Background

Background



Kenya's healthcare system is structured hierarchically, with the lowest stratum being made up of community health workers and dispensaries, with complex cases being referred to higher levels of facilities within the healthcare system. It can be divided into three categories: public providers, private non-profit organisations (including faith-based and mission hospitals as well as local and international NGOs), and private for-profit healthcare providers. The Ministry of Health accounts for 42.9% of total health facilities in the country, while the private sector accounts for 37.8%.



Kenya ascribes to Health in All Policies (HiAP), an intersectoral approach that facilitates decision-making among policymakers in order to maximise the positive health impacts of other public policies. The goal of this Kenya Health policy is 'attaining the highest possible standard of health in a manner responsive to the needs of the population.' The policy aims to achieve this goal by supporting the provision of equitable, affordable and quality health and related services at the highest attainable standards to all Kenyans. It is designed to take the country beyond the current health services approach and towards a primary healthcare approach, which remains the most efficient and cost-effective way to organize a health system.



Government expenditure on health has continued to increase over the years. The COVID-19 pandemic has seen the government further prioritize investment in critical health infrastructure, as well as try to address long-standing issues, such as workforce challenges. The created pandemic response task force – the National Emergency Response Committee on Coronavirus (NERCC) in particular – has allowed greater control over the health sector and represents productive channels for engagement.



The President's Big 4 Agenda has shifted the sector's focus towards achieving Universal Health Coverage (UHC), which has led to high political will in the health sector. As part of this, the Ministry of Health (MOH) has prioritized broadening access to services and scaling up the National Hospital Insurance Fund (NHIF). This has resulted in the realization that significant restructuring is required within the ministry and across the country's public health infrastructure.



As the impact of Covid-19 continues, there have been measures set in place for funding in the health sector to support the needs of people living in poverty and vulnerable populations. Though the approach to the UHC implementation process remains incremental, the new COVID-19 related governance structures have brought the health docket into the president's immediate purview, which could potentially create both a barrier to coordinated policy formulation and an opportunity to engage on healthcare issues within the highest levels of government.



The UHC pilot phase was rolled out in four counties, yielding successes with regards to the recorded number of patients attended to. However, the pilot also revealed some of the policy hurdles the sector faces in terms of restructuring challenges at the NHIF; data management shortfalls, despite Kenya's eHealth Policy; and a lack of health workers in the public sector.

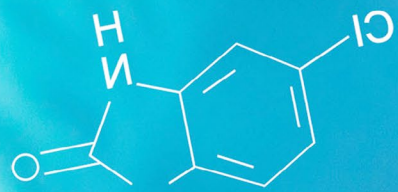


The commercial landscape nevertheless continues to experience rapid growth. The Kenyan pharmaceutical industry is currently the largest producer of pharmaceutical products in the Common Market for Eastern and Southern Africa (COMESA) region, supplying about 50% of the region's market. ¹The country has also been termed as a promising market for medical devices – almost all medical devices are imported and, as many healthcare facilities require modernization, demand for medical devices remains high.



Despite causing massive disruptions of operations, the COVID-19 pandemic stirred local manufacturers to take up the production of Personal Protective Equipment (PPE), which has continued to grow and now holds great promise for enterprise development in the country.

¹Kenya Pharmaceutical Sector Diagnostic Report, 2021



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Sector Policy Hurdles

Sector Policy Hurdles

4.1 Sectoral and Structural Changes

There have been challenges regarding deep institutional restructuring and intergovernmental coordination. Since the implementation of the UHC Pilot, the NHIF has experienced restructuring delays. The initial plan aimed to repurpose the NHIF and provide national coverage to all citizens. This was disrupted by capacity issues and concerns around corruption, resulting in a shift towards free service delivery based out of the Ministry of Health.

The Parliament passed the NHIF Bill which states every adult Kenyan has to make an annual compulsory KES 6,000 contribution to NHIF. It also seeks to make it compulsory for every Kenyan above 18 years to contribute to and become a member of NHIF – a remodeled universal health coverage (UHC) scheme for outpatient and inpatient services, including maternity, dialysis, cancer treatment and surgery.

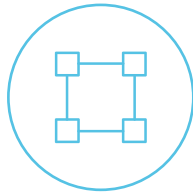


The planned mandatory membership will be an upgrade of the scheme whereby only workers in the formal sector are compelled to join and employers are obligated to match workers' monthly contributions to the fund.

However, this has been met with resistance from private sector players who wish to maintain the status quo, fearing loss of revenue as mandatory contributions towards NHIF will discourage citizens from taking up additional insurance from private sector players, or cancelling their current insurance subscriptions due to the cost implications. Additionally, intergovernmental wrangling, particularly over budgetary allocations and functions, has continued to hamper the implementation of UHC.

4.1.1 Impact on the Sector

Sectoral challenges have contributed to setbacks in several key areas:



Supply Chain



Understaffing in Facilities



Healthcare Financing



Innovation and Technology

Additionally, structural challenges such as the restructuring of the NHIF have **contributed to hindrances in the rollout of the Universal Health Coverage Program and hampered affordable and quality service delivery of health care services especially in government-run facilities.**

Consequently, a lack of quality service delivery in government facilities has over the years seen an increase in the number of private healthcare facilities. Services provided at private facilities are prohibitively expensive without the assistance of a comprehensive health insurance policy which limits accessibility, especially to the more vulnerable population.

4.1.2 Impact on Investment Landscape



Deterring investment - For investors, challenges such as the lack of intergovernmental coordination and institutional restructuring hampers the ease of doing business, due to the unclear processes, procedures and requirements posed by different government agencies at the national and county levels. This may deter their decisions to invest as they opt for markets that are easier to navigate.



Increasing complexity: Furthermore, structural challenges increase the complexity of the operating environment. Restructuring delays such as that of the National Hospital Insurance Fund have brought about uncertainty in the sector especially for private sector players such as health insurance firms. Currently, most private hospitals get 80 per cent of their income from the insurance sector, and the reforms may require that private hospitals, insurers and investors restructure their business models.

4.1.3 Policy Position

Robust policy intervention to address sectoral and structural challenges is critical to the advancement and investment attractiveness of the sector specifically addressing intergovernmental coordination especially between county -sub county up to ward level, developed in partnership with the Council of Governors.

4.1.4 Policy Recommendations

The government has recently made progress on finalizing the National Hospital Insurance Fund Act. In September 2021, members of parliament passed the NHIF Amendment Bill which will see all adults compelled to pay Sh500 monthly or Sh6,000 annually in a remodelled Universal Health Coverage (UHC) scheme for outpatient and inpatient services, including maternity, dialysis, cancer treatment and surgery.

The MPs however rejected the amendments by the National Assembly Committee on Health, which sought to have the national and county governments foot the bills for 5.1 million poor households.



We recommend that the amendments undergo further consultations with the private sector, especially on the financing aspect. Coordinated public-private partnerships between the government and private sector bodies and systems for health financing offer significant opportunities for accelerated improvements and have been relatively successful in lower-middle-income countries such as Lesotho. There lies an opportunity for Kenya to adopt best practices in order to successfully address financing challenges and aspects of service provision.



Furthermore, there is a need for increased dialogue between the Council of Governors and the National Government in order to address intergovernmental challenges. The need to strengthen the Health Sector Intergovernmental Forum which provides a platform for health stakeholders to discuss, consult, collaborate and build consensus on broad health issues affecting the country, and this should be leveraged by health sector players especially the government to address structural challenges.



4.2 Poor Quality, Management & Availability of Health Data

Despite data management being enshrined in Kenya's eHealth Policy since 2011, the health ministry has been unable to get a clear picture of national operations, driving up mismanagement and corruption. These issues are exacerbated by a lack of coordination, as well as increasing competition between the national and county governments. Existing data management initiatives, such as the Kenya Health Information System (KHIS) - developed with support from several development partners such as the Bill & Melinda Gates Foundation – is still in use but faces serious challenges in collecting clean and reliable data from clinics and operations at the subnational level.

This is because at the subnational level, data collection is paper based. Aggregate data and patient data remains in paper registers in the health facilities and patients have no access to their own data as prescribed by the Data Protection Act.

In addition, there is lack of consensus on data sharing protocols such as codes for each moving part in the health system i.e. patient, health facility, diagnosis, and interventions. Most importantly, Kenyans still lack a unique identifier.

4.2.1 Impact on the Sector

The inefficiencies due to unavailability or poor data management impacts the quality of healthcare, especially at lower-level health care facilities. This in turn increases operational and patient costs as diagnosis may be delayed due to a lack of up-to-date patient history and information. Additionally, the lack of real time data implies that public health decisions often rely on adjusted regional and national estimates. This impacts the decisions that are made in the sector.

Further, the lack of data sharing between health facilities and with the patient exerts extra costs on both the patient and the health system as unnecessary repeated procedures are carried out each time the patient visits a new health facility. The scattered data picture cannot allow for patient level analysis, further putting the patient at risk of missed treatment opportunities and sometimes even missed safety signals such as adverse reactions to medication.

An important shortfall of health data management in the sector has been lack of visibility of private sector data sets. Reporting to the KHIS by private sector is neither adequately incentivized nor enforced. With private sector providing approx. 50% of health services, this means that large swathes of data that would enrich decision making at national level are missing from the central database i.e., the KHIS.

Another issue with the KHIS is that it has not prioritized reporting of non-communicable diseases to the same level as communicable diseases, yet NCDs continue to bite deeper and deeper into the resources of the health system as well as those of families.

4.2.2 Impact on Investment Landscape



Without streamlined data management, forecasting for health services, tracking health trends in certain areas or among specific populations, and developing proactive measures to counter rising health issues becomes a challenge. The poor quality of health sector data **limits investment opportunities** due to limited information on health market dynamics which is critical to investment decisions.



Additionally, investors are unable to establish the technology and innovation needs in the country, which in turn **limits the growth of the sector**, as new medical advancements are not made available to the country.

4.2.3 Policy Position

Kenya's eHealth policy was developed to enhance data management in the sector. The government needs to be more committed, and work in partnership with the private sector to implement technology systems across the country as enshrined in the eHealth policy. This will contribute towards improved service delivery in the sector especially in remote areas, supporting advancements in technology and innovations such as telemedicine.

4.2.4 Policy Recommendations



To address data management shortfalls in the sector, **effective partnership on health information processes** is needed within the country. The key to achieving this is the integration of data collection and dissemination through partnership in the health information process amongst all health service providers both public and private.

It will be key for the government and private sector to collaborate on the development of frameworks and processes that will facilitate the development of effective data management in the sector.

This process should be supported by the integration of various sub-systems linking information, up to the community level alongside stakeholders' fora to foster partnership in health information system activities at both county and national levels.

Lessons can be learned from the remarkable data visibility provided by the mChanjo platform that has contributed to the success of COVID-19 vaccine roll out in the country. Notably, the platform provides visibility of patient level data to both the patient and the health system, while giving control to the patient to amend and download their data.

At the same time, at national, county and facility level, aggregate data is visible and trend analysis easy to achieve, an important requisite for forward planning. The system and infrastructure of mChanjo can be replicated to expand to other health indicators of interest.



Guidelines and a legal framework for reporting and feedback on health information. Policy frameworks should ensure that there is a framework to report and give feedback on information to enhance data management and this should be done in a **standardized and harmonized manner**. Moreover, giving feedback such as reports down the value chain to those who submit the data motivates them to provide even more reliable and timely data.



Implementation for health management information systems to provide for reliable and timely information which will support in planning and monitoring of health services.



Adequate resource allocation for establishment and sustainability of eHealth agenda. The necessities will be such as recruitment of staff in right numbers, computers, stationery, communication equipment, systems and staff development, reports and communication costs.



4.3 Lack of Adequate Human Resource Capacity in the Public Sector

The health workforce in the public sector has been characterized by critical shortages, uneven distribution, and an inadequate skill mix. Furthermore, devolution has exposed the lack of ground-level healthcare workers at the county level. There is a shortage of community health workers, nurses and doctors.

This issue has seen strikes persist in the sector, as health workers protest underfunding, understaffing and drug shortages. In addition, the sector lacks a coordinated framework for employing, regulating and compensating other necessary cadres of health workers. For example, out of 44 cadres, only 12 have regulatory bodies. Whilst the law provides for emergency care as a right to every Kenyan, there is lack of adequate regulation of emergency medical technicians.

4.3.1 Impact on the Sector

The health workforce in the public sector has been characterised by critical shortages, uneven distribution, and an inadequate skill mix. Furthermore, devolution has exposed the lack of ground-level healthcare workers at the county level. There is a shortage of community health workers, nurses and doctors. This issue has seen strikes persist in the sector, as health workers protest underfunding, understaffing and drug shortages.

Inefficient delivery of services as most health facilities have limited patient capacity, this has been especially evident during the Covid-19 pandemic.

Lack of delivery of specialized health care which has seen patients diagnosed with conditions requiring specialized treatment seek treatment outside the country. This in turn has limited the growth of the sector as there is no capacity building for skills gaps within the sector.

Increased cost of healthcare with limited healthcare providers. The sector has seen an increase in the cost of services due to the limited availability of human resources and drug shortages. Healthcare facilities are forced to charge higher rates for services in order to meet the demand for inpatient care. Specialized doctors who are also scarce have been seen to charge very high rates due to the high demand for their services.

4.3.2 Impact on Investment Landscape



Investment Deterrent: A lack of adequate human resource capacity for health is a major deterrent to potential investors. Especially for investors seeking to build health facilities, they may opt not to invest in the country as there will be challenges in staffing facilities to provide services to patients.



Limited investment opportunities: For successful adoption of advancements in health technology, access and capacity building is key. However, with insufficient human resource capacity, opportunities to train already existing health care workers exposing them to new technologies is challenging, hence investors looking to use new technologies may experience limitations in skills capacity and opportunities to deploy the same.

4.3.3 Policy Position

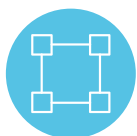
The policies and strategies to address the lack of human resources for health care need to be an integral part of the health systems' strengthening agenda. This is now more critical if Kenya is to make significant progress towards the attainment of universal health coverage, health-related Sustainable Development Goals, and realization of the right to health care as envisioned in the Constitution 2010.

4.3.4 Policy Recommendations



A national plan to grow the health workforce should be developed.

This should also involve the highest level of leadership as it will require a comprehensive plan for an effective health workforce, and commitment of the necessary funds. Funding must not only cover health service providers, but also the management and support workers who provide crucial services to the health system. The development of the national plan should integrate both the public and private sectors.



A Framework for direct investment in training and support for health workers is needed.

The government should develop a framework to continually train and upgrade health workers, especially at the community level and volunteers through workshops, seminars and short courses to equip them to offer specialised health services.

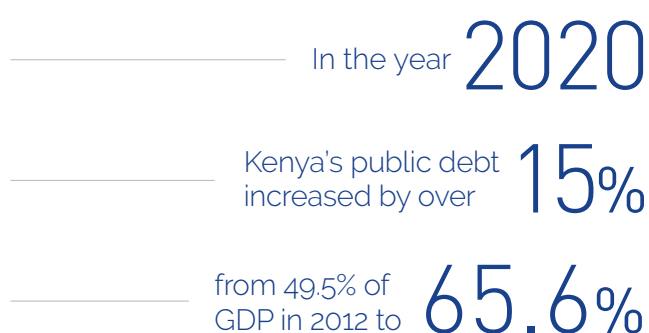


The government should target investments in the right areas of the health delivery system such as in health promotion and prevention, including measures to ensure that more people are attracted to work in the health sector.



4.4 Health Financing

Kenya is grappling with rising healthcare costs and increased demand for healthcare services in the face of ongoing budget constraints. The onset of the COVID-19 pandemic further brought to light the lack of adequate financing in the sector. Furthermore, insufficient financing has impacted the progress of aspects of UHC under the Big 4 Agenda, a problem which has been attributed to the country's increasing debt burden.



However, public-private partnerships (PPPs) have been proposed as the solution to funding gaps.

4.4.1 Impact on the Sector

The increased cost of healthcare services: The out-of-pocket payments are a barrier to accessing health services, especially in lower income earning areas.

Exposure to donor funding: Kenya faces serious donor dependency in several key sub-sectors of its health system. A report by the Brookings Institute indicates that from 2001-2016, donor spending was at least 50 per cent greater than domestic government expenditures for health. In some years (e.g. 2005-2006 and 2009-2010) donors spent double the amount spent by the government of Kenya on health. It also indicates that external financing makes up more than half of all funding for immunizations, tuberculosis (TB), and HIV, where for every dollar spent by the Kenyan government on immunizations, TB, and HIV, donors spend 3.3, 2.8, and 1.7 additional dollars respectively.

4.4.2 Impact on Investment Landscape



Increased costs of investment: Funding gaps in the sector translate to poor quality of service delivery in the sector, drug shortages, lack of proper infrastructure of health systems among others. Hence for an investment to be successful potential investors may need to increase their financing allocations to gain returns as compared to countries with well-financed health sectors. This directly impacts their decisions to invest.



This also presents a great investment opportunity. It presents investors with avenues to partner with the government to provide financing towards identified funding gaps. It will also be easier for investors to enter into the market as they will be addressing immediate market needs.

4.4.3 Policy Position

There is strong evidence that health system spending contributes to better health outcomes. Health systems are an important component of the macroeconomy, both as an industry that provides a large number of jobs and as a key determinant of a productive labour force. Adequate and appropriate health sector financing will strengthen the Health systems and support societal well-being by enhancing social protection and reducing impoverishment associated with ill health

4.4.4 Policy Recommendations



Public-private partnerships (PPPs) for health systems financing have been recommended as a solution towards addressing financing gaps, especially in developing countries. PPPs are increasingly gaining traction in Africa. According to Healthcare and Economic Growth in Africa, a joint publication of the United Nations Economic Commission for Africa (UNECA), GBCHealth and the Aliko Dangote Foundation, African governments are turning to the private sector to improve quality and deliver value for money, build infrastructure, provide staff and training, raise quality, improve productivity, undertake social marketing, and enhance procurement. They offer accelerated improvements and have been relatively successful in lower and middle-income countries.



Increased budgetary allocation for the health sector: Ensuring adequate funds are available for all health programs is essential for meaningful progress toward universal health coverage (UHC). In this regard, the government needs to increase its healthcare budgetary allocation. This however will require political will as it may mean that other sectors face potential budget cuts especially in the face of economic challenges made worse by the Covid-19 pandemic.

4.5 National - County and Subcounty Dynamics

A report by the Kenya Institute for Public Policy Research and Analysis (KIPPRA) has shown that while there is a broad delineation of competencies between the two levels of government (as outlined in the Constitution of 2010 and the Kenya Health Policy) there is a lack of a clear legal framework for transferring resources and functions from the county level to sub-county levels, and, within the counties, the same lack of a framework for transferring resources between micro-units, such as wards. This has led to a concentration of resources at county headquarters health facilities, while the sub-county facilities remain either under-resourced and or under-supported. Additionally, there have often been funding delays and budgetary allocation challenges between national and county governments. Delayed funding to counties has often disrupted the provision of services in the devolved units and has seen the Council of Governors (COG) threaten to trigger a shutdown in the units in protest of the national government's low disbursements.

4.5.1 Impact on the Sector

Sub-optimal resource allocation: Health care is a devolved function. The major challenges noted in the post-devolution era within the health sector include inadequate resources/funds from the national government and understaffed health facilities. These challenges have led to increased incidences of strikes which disrupt service provision.

Loss of trust in the public health system: The recurrence of strikes in the public sector and the disruptions brought by the prolonged strikes contributes to a 'loss of trust' from the public in the public sector that might have long term effects on treatment-seeking and ultimately the public health system. This is evident as more of the population continues to see private health care treatment.

Insufficient service delivery especially at the community level in remote areas. As sub-county facilities are under-resourced and under-supported due to a lack of proper framework for the transfer of resources, health care service delivery is not sufficient for the population, especially in remote areas reliant on community health workers (CHWs) programs. This also results in unaffordable alternative options for the poor.

4.5.2 Impact on Investment Landscape



The lack of a clear legal framework for the transfer of resources and functions from county to sub county to ward level presents a complex environment for investors. This may **discourage potential investors** especially those seeking to work with county governments due to uncertainty in service provision.



Additionally, as the dispersed resources are mainly concentrated in county headquarter health facilities, there is a **limitation of investment opportunities**, due to the lack of infrastructure and resources at lower levels such as wards.

4.5.3 Policy Position

There is a need for a revised policy framework to address the gaps in the transfer of health resources from the national to the county level. This framework should be comprehensive to cover sub-county and ward levels. The key is a collaboration between the Council of Governors and National Ministries to ensure that the policy frameworks are implemented. Additionally, the National Treasury should disburse funds to the counties on a timely basis to ensure that budget implementation is not adversely affected. Delayed funding has impacted economic growth, especially at the county level, because not many investments were made in key areas such as infrastructure and health.

4.5.4 Policy Recommendations



Adoption of systematic monitoring of different health system components and proactive thinking around possible effects of interventions and policies impacts. This will be critical in the development of a revised policy framework to address the gaps in the transfer of health resources. The process should involve engagements between the Council of Governors, private sector and the national Ministry of Health to build consensus for the review.



County and national governments need to rebuild relationships with healthcare workers' unions and include them in the development and implementation of policies that affect health workers, as they seek to streamline coordination. Careful consideration of the compensation packages of health workers is necessary to ensure fairness within and across cadres, and the creation of a conducive working environment to offer quality services at all levels from national - county- sub-county and ward level.



There is a need for a **review of the allocation of resources to counties**, to ensure that counties have sufficient resources to enable them to provide optimal services. This process would include consultation with key stakeholders overseen by the Commission on Revenue Allocation.



Allocation of resources to CHW programmes to provide for rigorous monitoring, evaluation, and implementation research to enable CHW programmes to continuously improve their quality and effectiveness.



4.6 Lack of Alignment Between Regulatory Agencies

Due to the duplicity of roles played by regulatory agencies in the sector, a need for harmonized standards and procedures has been cited. The Pharmacy and Poisons Board is mandated to ensure the compliance of standards for pharmaceutical products manufactured in the country, as well as those being imported. This mandate also falls under the Kenya Bureau of Standards, which has the authority to test imported and locally manufactured commodities in order to determine whether such commodities comply with quality standards. Furthermore, the Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), through legal notice 113 of 2011, is mandated to regulate all in-vitro diagnostics used in the country. It also screens, validates, certifies and registers products used in laboratory science practice - mandates which also fall under the Pharmacy and Poisons Board. This duplicity has led to an expanded bureaucratic process.

4.6.1 Impact on the Sector

Delays in approvals for health sector commodities: With misalignment between agencies and overlaps in mandates, health sector companies often experience delays in approvals, due to the numerous processes they must undergo to gain approvals and validation for use of their imported commodities. This also compromises product availability in the market due to delayed timelines.

Increased costs of doing business: Lack of streamlined mandates have seen each regulatory agency develop its approval processes with cost implications attached. This in turn significantly raises the cost of business operations especially if similar processes are being undertaken by more than one regulatory agency.

4.6.2 Impact on the Investment Landscape



Unfriendly business environment: Lack of streamlined compliance systems often lead to lengthy bureaucratic processes, which potentially deter investors due to challenges in doing business. With key regulatory agencies duplicating mandates in terms of testing, approval of standards, and compliance, there is an increase in the length and cost of the processes which may negatively impact investment decisions.

4.6.3 Policy Position

Clear, simplified and harmonized standards and procedures for approvals and compliance will ensure cost- effective, expedited services within the health sector. The duplicity of roles by regulatory agencies has presented increased costs for business within the sector in addition to unnecessary delays in the clearance of commodities, especially for imports.

4.6.4 Policy Recommendations



Harmonize regulatory jurisdiction/mandates for easier compliance.

This should be informed by stakeholder consultations with industry players who are impacted by the duplicity of roles and supported by advocacy from industry associations.



Enhance digitization to streamlined application and approval processes:

It is key for the government to enhance the digitization of applications, and approvals in order to expedite regulatory approvals and inspections.



Publication/gazette of fees for various testing procedures: This will allow potential investors to have a clear picture of the cost implications in terms of testing for imported and locally manufactured commodities. The harmonization and streamlining of regulatory processes should involve close collaboration with the private sector. The expertise and experience of global best practice retained by private sector can be utilized by the government to design a more effective regulatory system.

4.7 Illicit and Counterfeit Trade

Trade in counterfeit and contraband goods remains a major problem for Kenya, despite a decade of unprecedented legal and institutional efforts to control it. COVID-19 has specifically shone a spotlight on the trade in illicit health products. Proliferating unregulated chemists constitute the major centers of trade for these illicit drugs, compounded by consumers who seek to purchase the cheapest goods and services on offer.

4.7.1. Impact on Sector

Limited sector growth: Illicit and counterfeit trade limits growth of the sector because it impacts competitiveness of legitimate products as counterfeit products are often sold at a lower price.

Increased cost of healthcare for citizens: In the long run, counterfeit products negatively impact the health of the general population as substandard medication leads to recurring illness.

Tax losses for the government: As counterfeit products do not follow regulated channels of distribution, government revenues suffer loss of taxes and customs duties.

Lack of regard for quality assurance leading to procurement irregularities: As counterfeit products are unregulated and reach the market via uncontrolled distribution channels, there is no regard for quality assurance, which may be harmful to the users. Furthermore, the lower price of counterfeit health products promotes procurement irregularities in the healthcare system, as agencies purchase substandard products in order to save expenses which are not accounted for.

4.7.2 Impact on Investment Landscape



Investor Deterrence: Counterfeit products lead to unfair business practices and created a skewed competitive landscape. As a result, investors especially pharmaceutical manufactures, may shy away from entering or expanding in the market due to unfair competition.



Undermine intellectual property rights: Within the large counterfeit market in Kenya, there is lack of intellectual property rights protection - production of counterfeit drugs infringes on patents owned by international pharmaceutical companies.

4.7.3 Policy Position

There is need for stronger enforcement and surveillance against illicit and counterfeit trade to safeguard the interests of consumers and to ensure that the production or import of illicit/counterfeit products are actively combatted.

Additionally, there is a need for policy review to ensure streamlined processes and enhance collaboration by government agencies, especially when it comes to prosecution of illicit/ counterfeit traders in the market.

4.7.4 Policy Recommendation



Seal loopholes that facilitate production and entry of counterfeits into the Kenya market: There is need for the government to strengthen border surveillance and enforcement in order to ensure no counterfeit goods are imported into the country. Furthermore, there is need for more collaboration in data and intelligence sharing, joint enforcement and joint prosecutions by key institutions mandated with inspection and quality control of manufactured products – including, Kenya Bureau of Standards; the Anti-Counterfeit Agency; the Kenya Revenue Authority; and the Kenya Ports Authority.



Strengthen capacity of key institutions and government agencies to combat illicit trade

- Kenya has elaborate policies and laws to safeguard intellectual property and institutions to support enforcement of laws, but trade in counterfeits is still in place. This is often attributed to a lack of human resource and capacity, especially when it comes to enforcement. We recommend that there is increased budgetary allocation to government agencies tasked with combatting illicit trade to increase their capacity.



Development of an illicit trade index which will provide evidence of pricing and actual illicit trade practices

4.8 Inadequate Systems and Incentives to Grow the Local Manufacturing Sector for the Production of Health Products and Technologies

The pandemic highlighted the importance of self-reliance in access to health products, information systems and technologies (HPTs) for African countries, including Kenya. There was an evident gap in the availability of HPTs, which brought to light the limited government incentives and system support to grow local manufacturing of health products.

4.8.1 Impact on Sector

Limited sector growth: Lack of a favorable environment for local manufacturing of HPTs diminishes sector growth as there are inadequate opportunities to build local capacity, create employment and develop local innovative solutions. Manufacturing was one of the pillars of the Big 4 Agenda.

Inadequate accessibility and affordability: As much as there have been efforts to revitalize local production of HPTs, imports continue to grow faster than exports, limiting accessibility and affordability. Imported health products come at a higher price than locally manufactured products and may not be readily available and accessible by majority of the population, especially lower income earners and those in rural areas.

4.8.2 Impact on Investment Landscape



Decreased foreign direct investment:

With limited incentives to develop local manufacturing of HTPs, investors will not be compelled to forge partnerships with local manufactures, which could improve FDI flows into Kenya. This further hampers the transfer of knowledge and innovation in the sector.

4.8.3 Policy Position

There is a need for a progress review of the implementation of the HPT Supply Chain Strategy 2020 -2025, in order to identify challenges and areas of support. The strategy offers ample solutions and incentives, but its implementation has been inadequate, leading to a tangible gap in the availability of local health products and technologies.

4.8.4 Policy Recommendation



Collaborate with private sector to realize The HPT Supply Chain Strategy 2020-2025. The strategy speaks to incentives that the government has put in place to support local manufacturers to scale up their production. Such efforts include exemption of import duty on active pharmaceutical ingredients (API) and all finished pharmaceutical products, as well as application of reservation and preferential procurement regulatory provisions in the Public Procurement and Assets Disposal Act, 2015. However, there is need for the government to collaborate with private sector players to implement key aspects of the strategy such as further fiscal incentives – for example,

- VAT exemptions to lower costs of production;
- Streamlined and fast tracked processes for pre-licensing requirements for local manufacturers;
- Support for the development and
- Strengthening of knowledge exchange between industry players and government; and support for attracting FDI.

“The pandemic highlighted the importance of self-reliance in access to health products, information systems and technologies (HPTs) for African countries, including Kenya.”



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Resolution Recommendations

Resolution Recommendations

The policy hurdles within the health sector can be addressed through the following measures:



Public-private partnerships (PPPs): Challenges such as financing in the healthcare system can be addressed through partnerships between the public and private sectors. According to Healthcare and Economic Growth in Africa, African governments are turning to the private sector to improve quality and deliver value for money, build infrastructure, provide staff and training, raise quality, improve productivity, undertake social marketing, and enhance procurement. Successes have been achieved in countries such as India which adopted more comprehensive service delivery PPPs, where not only are the facilities developed and improved by the private sector, but services are provided. The government can leverage on private sector industry players to support PPPs in the health sector. Prospects for PPPs are favourable in equipment supply, eHealth, training and education, health insurance and establishment of new private hospitals.

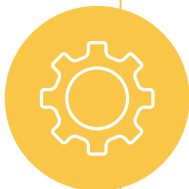


Public-private dialogue (PPDs): Engagement between public and private sectors are key to ensuring a favourable environment for doing business. Consistent dialogue with various arms of government presents an opportunity to address sector-specific priority issues relating to policy, business and operations affecting private sector companies. Benefits from PPDs can be wide-ranging and include buy-in for reform; evidence-based policymaking; inclusive and participatory policy-making, easier policy implementation and increased trust and understanding between the public and private sectors. In this regard, the recommended working group would provide a valuable mechanism in which to embed long term effective dialogue and collaboration.



Enhancing technology to enhance health service delivery:

Healthcare systems continue to undergo ongoing pressure to increase the quality and efficiency of care and find new ways to use data, systems and distributed networks of providers to provide quality health services. Technology provides the opportunity to enhance health care systems with proper data management and support innovations such as telemedicine. Additionally, Kenya has high mobile phone penetration, which creates a market for mHealth products such as connected devices and patient tracking. Private sector have exposure to technology advancements especially in health data management and are well placed to offer advisory to the government on best practice in this regard.



Supporting capacity building for the health sector workforce:

Challenges in human resource capacity can be addressed by the development of a framework and national plan to grow the workforce. A key pillar should be direct investment in training and support for health workers. The government should continually train and upgrade health workers, especially at the community level and volunteers through workshops, seminars and short courses to equip them to offer specialised health services. There is an opportunity for the private sector to support the government in bolstering training programs for community health workers and professions, especially with the uneven distribution and inadequate skills mix.



Lobbying and advocacy to drive regulatory reforms to address structural and sectoral challenges in the sector.

Industry lobbies and associations will be key actors to push for favourable legislation that will be beneficial to the sector. This advocacy will be required to take place with regulators, policymakers and parliamentarians who shape and pass legislation, policy and regulation. Private Sector can formulate proposals and lobby key government ministries, agencies and legislators in collaboration with other industry associations and its members to push for a conducive regulatory framework.





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