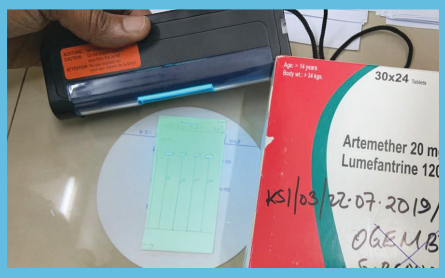
REPUBLIC OF KENYA

MINISTRY OF HEALTH

HEALTH PRODUCTS AND TECHNOLOGIES

SUPPLY CHAIN STRATEGY 2020 - 2025



REPUBLIC OF KENYA

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Health Products and Technologies Supply Chain Strategy 2020 - 2025

The Health Products and Technologies Supply Chain Strategy 2020 - 2025
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Corona


KENYA MEDICAL SUPPLIES AUTHORITY
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Healthy
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ACRONYMS

ADR	Adverse Drug Reaction
AG	Attorney General
AMU	Appropriate Medicines Use
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
ARV	Anti-Retroviral
AWaRe	Access, Watch and Reserve
AWP	Annual Work Plan
BMGF	Bill and Melinda Gates Foundation
CAS	Chief Administrative Secretary
CDF	Constituency Development Fund
CEC	County Executive Committee
CECM	County Executive Committee Member
CEO	Chief Executive Officer
cGMP	Current Good Manufacturing Practice
CHMT	County Health Management Team
CMIS	Commodity Management Information System
CPD	Continuous Professional Development
CoH	Chief Officer of Health
COMESA	Common Market for Eastern and Southern Africa
CS	Cabinet Secretary
DG-HS	Director General for Health Services
DHIS2	District Health Information Software
DMS	Director of Medical Services
DPs	Development Partners
DPS	Director of Pharmaceutical Services
DSRS	Department of Standards and Regulatory Services
DVS	Director of Veterinary Services
EAC	East African Community
EHPT	Essential Health Products and Technologies
EMMS	Essential Medicines and Medical Supplies
ERB	Ethical Review Board
ESC	Emergency Supply Chain
EVM	Effective Vaccine Management
FBO	Faith-Based Organization
FDA	Food and Drug Authority
FKPM	Federation of Kenya Pharmaceutical Manufacturers
F & Q	Forecasting and Quantification
FTAs	Free Trade Agreements
GAVI	Global Alliance for Vaccines and Immunisation
GDP	Good Dispensing Practice / Good Distribution Practices / Gross Domestic Product
GHE	Government Health Expenditure
GoK	Government of Kenya
GPP	Good Pharmaceutical Procurement (Principles)
GPP	Good Prescribing Practices
GSPOA	Global Strategy and Plan of Action
HCIT	Health Care Information Technology
HF	Health Facility
HPT	Health Products and Technologies
HSSF	Health Sector Services Fund
HTA	Health Technology Assessment
ICC	Inter-Agency Coordinating Committee
ICT	Information and Communication Technology
IDF	Import Declaration Form
IGF	Inter-Governmental Forum
INN	International Non-proprietary Name
IP	Intellectual Property
ISO	International Organization for Standardization
KEBS	Kenya Bureau of Standards
KEML	Kenya Essential Medicines List
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KEMSL	Kenya Essential Medical Supplies List
KEPH	Kenya Essential Package for Health
KES	Kenya Shillings
KFDA	Kenya Food and Drug Authority
KHSSP	Kenya health Sector Strategic Plan
KNBS	Kenya National Bureau of Statistics
KNPP	Kenya National Pharmaceutical Policy
LMIS	Logistics Management Information System
MDGs	Millennium Development Goals
MDR-TB	Multi-Drug Resistant Tuberculosis
M&E	Monitoring and Evaluation
MEDS	Mission for Essential Drugs & Supplies
MES	Managed Equipment Services
MOE	Ministry of Education
MOH	Ministry of Health
MOSCH	Ministry of Sports Culture and Heritage
MOTI	Ministry of Trade and Industrialization
MOU	Memorandum of Understanding
MTC	Medicines and Therapeutics Committee
MTEF	Medium Term Expenditure Framework
MTPP	Medium Term Procurement Plan
NA	Not Applicable
NACADA	National Campaign Against Drug Abuse Authority
NCDs	Non-Communicable Diseases
NMTC	National Medicines and Therapeutics Committee
NQCL	National Quality Control Laboratory
OTC	Over-The-Counter
OIE	World Organization for Animal Health (formerly Office International des Epizooties)
O&M	Operation and Maintenance
OR	Operational Research
PCV	Pharmacovigilance
PFMA	Public Finance Management Act
PHI	Public Health Inspector
PICC	Pharmaceutical Interagency Coordinating Committee
PMS	Post Marketing Surveillance
PPDA	Public Procurement and Disposal Act
PPB	Pharmacy & Poisons Board
PPHF	Policy Planning and Health Financing
PPRA	Public Procurement Regulation Authority
PS	Principal Secretary
PSK	Pharmaceutical Society of Kenya
PMIS	Pharmaceutical Management Information System
PQM	Promoting the Quality of Medicines Program

PvERS	Pharmacovigilance electronic reporting system
QA	Quality Assurance
QC	Quality Control
QPV	Quality Pharmacovigilance
QPPV	Qualified Person for Pharmacovigilance
RID	Research, Innovation and Development
R&D	Research and Development
SWAp	Sector-Wide Approach
TAM	Traditional and Alternative Medicines
THE	Total Health Expenditure
TM	Traditional Medicine
TOR	Terms of Reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWG	Technical Working Group
UHC	Universal Health Coverage
USAID	United States Agency for International Development
USFDA	United States Food and Drugs Agency
USP	United States Pharmacopeial Convention
VMTC	Veterinary Medicines and Therapeutics Committee
WHO	World Health Organization
WTO	World Trade Organization

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FOREWORD

The Kenyan Health Sector has been playing a critical role in providing health care services in response to the population needs in line with the Kenya Health Policy, 2014-2030's goal of attaining the highest possible health standards in a manner responsive to the population needs. Overall, the Health Sector strategic focus guided by the Country's blueprint, Vision 2030 and the Constitution of Kenya, 2010. The Kenya Vision 2030 aims to transform Kenya into a globally competitive and prosperous country with a high quality of life by 2030, while the Constitution of Kenya, 2010, guarantees the highest attainable standard of health as a right. The policy direction envisages that investments in health systems will be scaled up for improved health outcomes. One of the eight orientations/investment areas of the Kenya Health Policy (KHP) is Health Products and Technologies (HPT).

The HPT investment area seeks to ensure that effective, safe, and affordable health products and technologies are available and rationally used, while maintaining a strategic national health products and technologies (HPT) reserve. Policy direction regarding HPT is further elaborated in the Kenya National Pharmaceutical Policy of 2012 whose implementation pace has been slow. However, in line with the increased focus through the Universal Health Coverage (UHC) and the Sustainable Development Goals at the global level, this strategy seeks to provide clear direction on HPT supply chain agenda.

The Kenyan Government is implementing UHC as one of its four flagship programs dubbed "The President's Big Four Agenda". This program, which is in line with Sustainable Development Goals (SDG) 3, has an overarching goal of ensuring that all citizens have access to safe, effective, quality essential health care services, including affordable essential medicines and vaccines without going into poverty. Ensuring that effective, safe, and affordable health products and technologies are available and rationally used, is pivotal to a functioning health care system that supports the UHC agenda. As such, the policies, regulations, systems and practices regarding health products and technologies have a direct bearing on access to, quality and safety of healthcare services delivered to citizens in need.

Notably, the Ministry of Health working in collaboration with the 47 County Governments in Kenya has been driving a raft of reforms aimed at strengthening the national capacity to deliver the UHC agenda. These reforms include the establishment of the Division of Health Products and Technologies (DHPT) and transforming the Kenya Medical Supplies Agency into an Authority, thus increasing its autonomy and responsiveness to serve counties and public health facilities including the National Referral Hospitals. Key policies have also been formulated and coordination has been prioritized. Progress has been made towards improving the regulatory and governance environment, but challenges abound.

This inaugural HPT Supply Chain Strategy is therefore a sound response to these key challenges through providing a strategic direction for the sector in HPT supply chain for the medium term. The strategy seeks to improve coordination, elaborate strategic directions

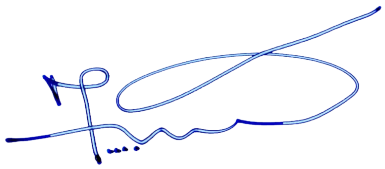
and investments, and enhance decision-making at the various levels of the HPT supply chain. The strategy was developed through a participatory process involving all stakeholders in health.

The strategic direction, crafted in the context of the overall health sector agenda, identifies the vision and approaches that underpin this HPT Supply Chain Strategy. The strategy envisions "A sustainable, resilient and responsive health products and technologies supply chain system" with a mission to provide a steady supply of quality and affordable health products and technologies through a functional supply chain system. This strategy identifies six key pillars for the attainment of the stated vision: enhancement of capacity for governance, regulation and quality assurance; establishment and sustenance of a robust HPT product selection quantification and procurement and distribution system; harnessing collaboration and partnerships at all levels for effective resource mobilization and implementation; embracing and adopting Information Communication Technology in all aspects of supply chain for HPT; Scaling up capacity for research, local production, and full exploitation of TRIPS flexibilities for Health Products and Technologies ; and strengthening human resource management and development for HPT supply chain.

Admittedly, the strategic planning process has been completed during the COVID 19 Pandemic, a period that offers crucial lessons particularly with regards strengthening of supply chain in terms of responsiveness of local producers, transparency, and accountability. The health sector will piggyback on the goodwill demonstrated in the development of this strategy to continuously engage and involve stakeholders including government agencies, manufacturers, universities, research institutions, traders, health practitioners and other civil society during implementation.

This strategy positions the sector to collaboratively take on the persistent challenges experienced in our complex HPT supply chain with a robust governance and service delivery framework.

I look forward to full implementation of this strategy as we work towards the achievement of our overall health sector goal outlined in the Kenya Health Policy 2014 – 2030 - the attainment of the highest standard of health in a manner responsive to the needs of the Kenya population.



Sen. Mutahi Kagwe, EGH
Cabinet Secretary
MINISTRY OF HEALTH

EXECUTIVE SUMMARY

The Health Sector Strategic focus in Kenya is guided by the Country's blueprint, Vision 2030 and the Constitution of Kenya, 2010. The Kenya Vision 2030 aims to transform Kenya into a globally competitive and prosperous country with a high quality of life by 2030, while the Constitution of Kenya, 2010, guarantees the highest attainable standard of health as a right. To support the achievements of the aspiration of Vision 2030 and the Kenya Constitution, 2010, the Kenya Health Policy, 2014–2030 has, as its goal, 'Attaining the highest possible health standards in a manner responsive to the population needs'. The Policy has eight orientations/investment areas, one of which is Health Products and Technologies (HPT). The HPT investment area seeks to ensure that effective, safe, and affordable health products and technologies are always available and rationally used , while maintaining a strategic national health products and technologies (HPT) reserve.

The situational analysis undertaken in preparation for this strategy has echoed findings from various reviews undertaken over the last decade – ranging from priority program reviews; facility assessments; KEMSA assessments; reviews preceding development of strategies for county health sectors, national referral institutions and key agencies in the HPT supply chain such as regulatory boards, academic institutions; as well as assurance reviews by Public Procurement Regulatory Authority (PPRA) and Office of Auditor General (OAG). On the positive side, the reviews appreciate the existence of guiding health and pharmaceutical policies, essential drugs list, clinical guidelines and protocols, guidelines for various aspects for commodity managements, establishment of agencies for supporting HPT supply chain such as KEMSA – a remarkable evidence that the Kenyan health sector has increasingly adopted and customized international instruments in the area of essential health products.

Despite these gains low implementation levels regarding the health products and technologies policy stipulations has been flagged of as a persistent concern. The issues identified include:

- Inadequacies in capacity for governance, regulation, and quality assurance
- Inadequacies in transparency and accountability across the HPT supply chain
- Opportunities to optimize product selection, quantification, procurement, and distribution building on promising practices in both public and private sectors
- Gaps in human resource management and performance management stifling delivery of HPT functions across both public and private sector
- Optimization of HPT information management systems to improve data availability, accessibility, and utilization across the entire HPT supply chain
- Opportunities for scaling up research and development, and local production capacity for HPT as well as exploitation of TRIPS Agreement flexibilities
- Inadequate coordination of stakeholders and partners for effective resource mobilization, allocation, and monitoring and evaluation

This strategy recognises that maintenance of the status quo is untenable in the context of shrinking resource envelope and increasing demand for accountability. It has therefore provided a sound response to these key challenges in HPT supply chain for the medium term. The strategy seeks to improve coordination, elaborate strategic directions and investments, and enhance decision-making at the various levels of the supply chain to enable it to move towards attainment of the Kenya Health Policy, 2014–2030 directions. The **Vision** of the HPT Supply Chain Strategy is "A sustainable, resilient and responsive health products and technologies supply chain system. The **Mission** is to provide a steady supply of quality and affordable health products and technologies through functional supply chain system. Six pillars will be pursued in the implementation of this strategy.

The capacity for HPT governance, regulation and quality assurance will be strengthened for improved oversight and accountability at all levels of the HPT supply chain. Of top priority is harmonisation of relevant legislation, and strengthening of governance structures for key agencies such as KEMSA, National Medicines Regulatory Authority, National Quality Control Laboratory (NQCL); and technical committees such as the NMTCs and County MTCs.

A robust HPT product selection, quantification, procurement, and distribution system for HPT will be established and sustained for improved availability and accessibility of HPT and overall health outcomes. Capacity for procurement, storage, and distribution will be enhanced in a rationalized manner for cost effectiveness. Additionally, a comprehensive program for promoting rational use of HPT will be developed and rolled out across all levels of the HPT Supply Chain.

Collaboration and partnerships at all levels of HPT supply chain will be enhanced and harnessed for effective, coordination resource mobilization and implementation. Coordination amongst players in the HPT supply chain will be enhanced through revitalizing the partnership and coordination organs at all levels. Engagement between the public and private sectors will be harnessed in support of the universal health coverage and towards equitable access for health products and technologies. In line with the obligations of the Constitution of Kenya, 2010, community engagement will be mainstreamed in the implementation of HPT policies with a view to empowering the population on rational use of HPT.

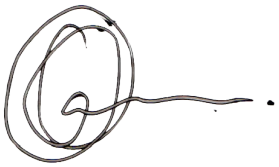
The sector will embrace and adopt Information Communication Technology in all aspects of supply chain for HPT. Leveraging on technology, and emphasizing on simplicity and coordination at all levels, the sector will improve efficiency in reporting and utilization of data for HPT planning and decision-making. Health workers at all levels will be empowered with a means to visualize/analyse the data submitted monthly in the national system and ensure continuous availability of life-saving commodities across health facilities.

Additionally, the sector will scale up capacity for local production of HPT and exploitation of TRIPS Agreement flexibilities for Health Products and Technologies. A structured program for strengthening human resource management and development for HPT supply chain will be rolled out. Core concepts on HPT supply chain will be incorporated in the pre-service and in-service curricula for health workers, and the capacity building programs harmonized.

Towards strengthening monitoring of implementation, a detailed implementation matrix specifying objectives, costed interventions to be pursued as well as expected results has been developed. This strategy will be translated into annual operational plans with quarterly targets. Quarterly reports of performance will be prepared to facilitate progress review against the targets included in this strategic plan. In terms of evaluation, the strategic plan will be evaluated at midterm and end term. Evaluation will take into consideration measures of relevance, efficiency, effectiveness, sustainability, and impact.

In terms of the implementation arrangements, this strategy envisages that the MOH's Division for HPT will be revitalized to serve as the anchor for coordination, establishment of various technical working groups; with the overall oversight provided by the HPT inter-agency coordination committee. County governments will be encouraged to prioritize the establishment of HPT supply chain coordination units domiciled in their health departments. Implementation of this strategy calls for mobilization of additional resources. This is especially true given the current implementation of Universal Health Coverage, and need for sustainability in health financing.

Dr. Rashid A.Aman
Chief Administrative Secretary
MINISTRY OF HEALTH



Dr. Mercy M.Mwangangi
Chief Administrative Secretary
MINISTRY OF HEALTH

ACKNOWLEDGEMENT

This first HPT Supply Chain Strategy is a product of collaborative effort of various stakeholders. The stakeholders who participated in various stages of development of this document include the Council of Governors, County departments of health, national and county health facilities, development partners and implementation partners, faith-based organizations, private sector, and civil society.

The Ministry of Health appreciates the support provided in the development of this strategy by various stakeholders. Particularly, the financial and technical support given by the United States Agency for International Development (USAID) through the Afya Ugavi Activity and the participation of the World Bank and Bill and Melinda Gates Foundation. Further, the support from Africa Resource Centre (ARC) in costing the strategy is acknowledged.

The Ministry of Health acknowledges the leadership and guidance provided by Dr. Patrick Amoth, the Director General of Health in the development of this strategy. Further, we applaud the HPT Supply Chain Strategy Technical Working Group who worked tirelessly with dedication despite the travel and meeting restrictions brought about by the COVID-19 Pandemic. I would also like to thank the staff of the Ministry's Division of Health Products and Technologies for their team work and commitment in the preparation of this strategy; particularly, Dr. Josphat Mbuva, the Head of the Division for effectively coordinating the process to its completion.

We are also grateful for the comments and insights provided by stakeholders at all stages of the development of this strategy. We call upon our partners and stakeholders to continue working closely with the Ministry of Health during the implementation of this strategy.

Susan N. Mochache, CBS
Principal Secretary
MINISTRY OF HEALTH

CHAPTER 1:
INTRODUCTION

CHAPTER 1

1.1 KENYAN CONTEXT

Kenya is a low middle-income country located in East Africa, bordering Ethiopia (North), Somalia (North East), Tanzania (South), Uganda (West), and South Sudan (North West). The country covers 580,895 square kilometers,and is divided into 47 counties administered through a devolved governance model. According to the 2019 Population and Household Census, Kenya had a population of 47.56 million with females accounting for 50.5 per cent, and average household having 3.9 members. The country has a high youthful population, with persons below the age of 35 years accounting for 75% of total population.

Kenya's Gross Domestic Product (GDP) was KES 9.74 Trillion in 2019. The major contributors to the GDP of the economy were agriculture, construction, manufacturing, financial and insurance services, accommodation and food services, ICT, education, mining and quarrying, wholesale, and retail trade. The country has registered average annual growth of 5.4% over the last five years. Notable is the growth in ICT sector fuelled by the youthful population, the mobile cellular penetration stood at 114.70 per 100 inhabitants in 2019, mobile network coverage at 89.1% and mobile transfers are well over KES 7 Trillion (KNBS, 2020). Poverty level dropped by 11 percentage points from 2005/2006 to 36.1% in 2015/2016 as per the Kenya Integrated Household Budget Survey. Notable variations exist with rural poverty rates at 40% compared to urban and peri-urban poverty at 28-29%. Regional variations are also significant with North Eastern part recording rates of up to 80% (KNBS, 2018).

Kenya's goal, as articulated in its blueprint, Kenya Vision 2030, is to be a globally competitive and prosperous nation with a high quality of life by 2030. This quest is in line with global commitments, particularly: the aspiration of a prosperous Africa based on inclusive growth and sustainable development as captured in the Agenda 2063 of the Africa Union Commission on the Africa We Want; the 172 Sustainable Development Goals (SDGs) for 2030 championed by the United Nations (UN). SDG 3 "ensure healthy lives and promote well-being for all at all ages" has ambitious target for reducing mortality from communicable and non-communicable diseases for all ages. The commitments include ensuring access to safe, effective, quality and affordable essential medicines and vaccines for all and supporting the research and development of vaccines and medicines for the communicable and non-communicable diseases that are prevalent in developing countries; as well as enabling access to HPT in accordance with the Doha Declaration on the TRIPS Agreement and Public Health.

1.2 KENYAN HEALTH SYSTEM

The health sector contribution to the national goal is outlined in the social pillar of the Vision 2030. The sector's goal is elaborated in the Kenya Health Policy (2014-2030) that provides direction towards attainment of the highest possible standards of health in a manner responsive to the needs of the population. The policy addresses the journey to achievement of fundamental rights relating to health, in the Constitution of Kenya, 2010 with emphasis on ensuring equity, people centredness and a participatory approach, efficiency, a multi-sectoral approach, and social accountability in the delivery of healthcare services. Universal Health Coverage (UHC) for all by 2022, one of the President's Big Four agenda, an initiative that commenced in December 2017, is aimed at addressing inequity and supporting the attainment of health outcomes.

Kenya has a devolved health system with national government having the core mandate of health policy, health regulation, national referral health facilities, capacity building and technical assistance to counties, while the counties are responsible for health service delivery. The system is organized into six levels of healthcare – community, dispensaries, health centres, primary hospitals, secondary hospitals, and tertiary hospitals. A total of 12,714 health facilities owned by the government, private sector and faith-based organizations, support health service delivery across these levels. These are complemented by about 5,840 registered retail pharmacies, and 5,215 community health units across the country. There are some state agencies that have specific mandate in the health sector — the Kenya Medical Supplies Authority (KEMSA) as the lead government supply chain agent for HPT, Kenya Medical Research Institute (KEMRI) responsible for coordination of health research, National Aids Control Council (NACC), National Cancer Institute of Kenya (NCI-K), Kenya Medical Training College (KMTC), National Hospital Insurance Fund (NHIF) as well as eight [1]regulatory bodies for professional practice.

The health sector policy lays out the following six broad policy objectives: i) elimination of communicable diseases; ii) reduction and reversal of rising burden of NCDs; iii) reduction of the burden of violence and injuries; iv) provision of essential health services; v) minimizing exposure to health risk factors; and, vi) strengthening collaboration with health related sectors. Progressive achievement of the objectives is through acceleration of investments and improved of access and quality in the following areas: health financing, health products and technologies, health information, health workforce, service delivery systems, health infrastructure, and research and development. The government of Kenya, both at national and county level, is boosting its focus on the role of community health units in delivery of health services.

1 There are eight health regulatory agencies established through acts of Parliament. These are: Nursing Council of Kenya (NCK), Medical Practitioners and Dentist Board (MPDB), Clinical Officers Council (COC), Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB), Pharmacy and Poisons Board (PPB), Public Health Officers and Technicians Council (PHOTC), Radiation Protection Board (RPB), and Kenya Nutritionists and Dieticians Institute (KNDI). Society of Radiographers of Kenya (SORK) is the only professional agency that represents radiographers in any professional forum. SORK vets radiographers for professional regulation in training and practice.

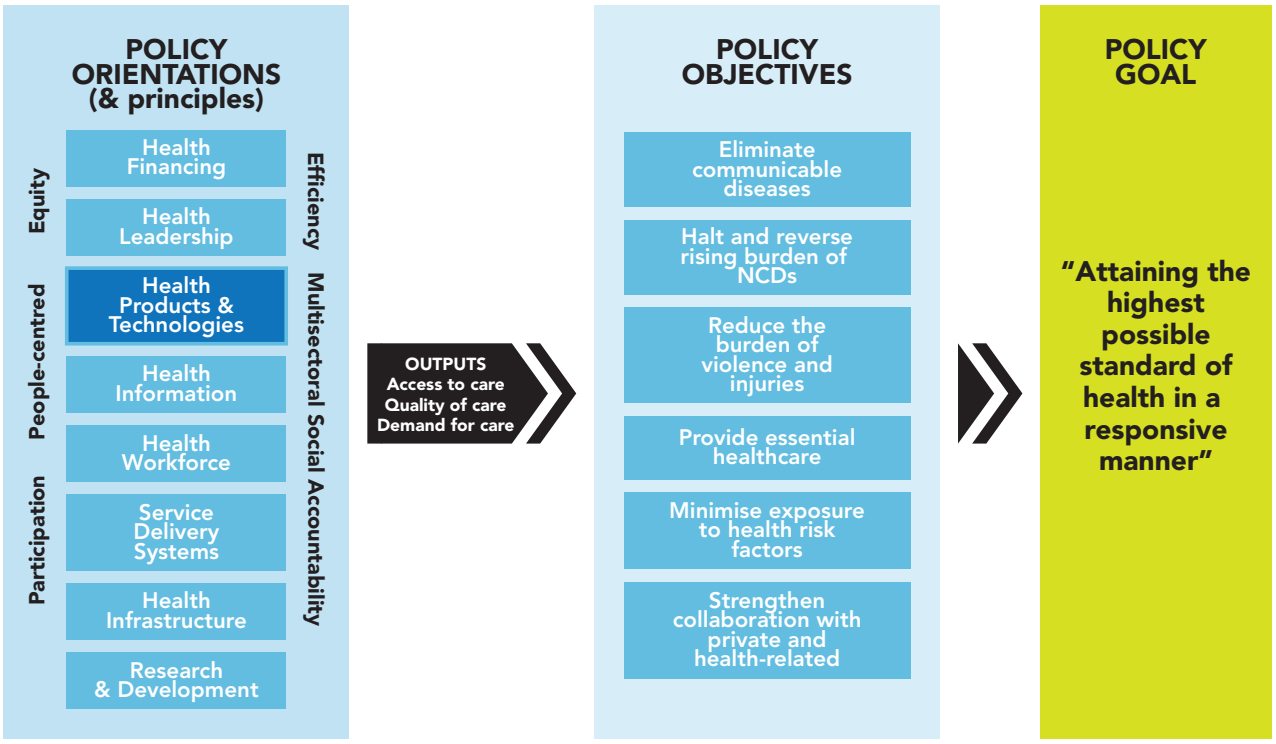


Figure 1 | Kenya Health Policy Orientations, Objectives, and Goals

Notably, the HPT pillar, that has significance across objectives and investment areas, lays out broad aspirations for developing effective and reliable procurement and supply systems to improve access to, and quality of HPT.

The country has recorded growth in training of health professionals and thus improved on the norms and standards for human resources for health. However, the current staffing levels are still below norms for all cadres other than nurses, in addition to having large disparities in distribution. Although various cadres of healthcare staff are involved in the management of Health Products and Technologies (HPT), majority are involved in ensuring rational use through prescribing and dispensing. Discharge of core supply chain functions of quantification, procurement, warehousing, and distribution has been coordinated by few cadres including pharmacists, pharmaceutical technologists, nurses, and medical laboratory technologists.

According to the 2015/2016 National Health Accounts, the Total Health Expenditure was estimated at KES 346 Billion and accounting for 5.2% of the nominal GDP while per capita health expenditure was KES 6,602. This is considered below the desired target investment of about KES 23,407 per capita for coverage of Essential Health Benefits. In terms of sources of financing, the government remains the biggest healthcare financier accounting for 33%, followed by households, donors, and corporations at 33%, 22% and 12% respectively. Donors investments are mainly concentrated on the priority public health programs. The government allocation to health has been increasing stabilizing at 7.5% of the national budget. Allocations to HPT account for 13% of the health budget. Under the affordable health for all initiative, there are deliberate attempts to improve health financing through pooling mechanisms and strategic purchasing. Health insurance coverage is still low at 19%, an estimated 4.9% of Kenyans incur catastrophic expenditure from out of pocket

healthcare payments while many others (28%) fail to seek treatment owing to affordability barriers.

Significant investments and progress have been made in Health Information System, particularly regarding strengthening data collection, data aggregation and transmission and overall quality of health-related data. Applying, web-based systems for data management and leveraging on improved mobile telephone networks coverage, utilization of the Kenya Health Information System (DHIS 2) has improved reporting rates. In FY 2017/2018, 90% of health facilities submitted complete reports while 83% submitted timely reports. Investments in infrastructure and equipment have also continued at both national and county level with the most visible ones in the public sector being construction of new health facilities, implementation of the Managed Equipment Service (MES) for provision of medical equipment to 120 hospitals.

The last sector strategic plan (KHSPP 2013-2017) review, and health facility assessments revealed mixed results in terms of service delivery achievements. These results have an apparent reflection of the effectiveness of the HPT supply chain. The RMNCAH program has registered significant achievements driven by the free maternity program and Linda Mama Initiative. Proportion of women attending at least four ANC visits rose to over 50%, proportion of deliveries under skilled birth attendants increasing by 5% to 65% in 2019. Immunization coverage has increased from 76% in 2016 to 79% in 2019. Infant and under five mortality rates have reduced to 39 and 52 per 1,000 live births, respectively. However, proportion of women of reproductive age accessing family planning services and commodities has stagnated at 43% owing to contraceptive commodity security challenges. The nutrition program registered improvements in Vitamin A supplementation (VAS) coverage from 44% in 2017 to 64.5% in 2019. Iron and folic acid supplementation (IFAS) supplementation stood at 69.6% in 2018 against a target of 80%.

In the HIV/AIDS program, the prevalence has been reducing and stood at 4.9% in 2019 with 1.1 million persons put on ART and over 400,000 lives saved. The proportion of HIV positive pregnant women receiving ARVs under the PMTCT program was at 94% in 2017/2018. The Malaria program reported reduction in prevalence of malaria morbidity from 14% in 2010 to 8% in 2015. The program has boosted its distribution of long lasting insecticide treated bed nets (LLINS), Artemether Combination Treatment (ACT), and Rapid Diagnostic Test kits (RDTs) thus leading to households' coverage with nets at 63%, and 84% of public health facilities having capacity for diagnosis of malaria. However, the burden for TB, based on prevalence survey of 2015/2016, had more than doubled prompting intensification of notifications and diagnosis. Overall morbidity from infectious diseases has been declining.

On the other hand, the burden of non-communicable diseases (NCD) has been rising with NCDs contributing over 50% of hospital admissions and over 55% of mortality. The 2015 STEPS survey and the 2014 KDHS revealed: low levels of screening for cancers with cervical cancer screening for women of 25-49 years below 20%; diabetes mellitus prevalence at 2%, hypertension prevalence and treatment coverage at 24% and 4% respectively. It is therefore evident that non-communicable diseases continue to pose a challenge to the responsiveness of the healthcare system in meeting the highest standards expected for all Kenyans. This is exacerbated by other factors such as the climate change, drugs resistance, income inequality as well as the emerging global pandemics like COVID -19.

1.3 HEALTH PRODUCTS AND TECHNOLOGIES SUPPLY CHAIN

Access to quality and affordable essential health products and technologies is pivotal to successful delivery of health services in Kenya. The effectiveness of the HPT supply chain in assuring security of HPT through delivery of HPT across all the levels of the healthcare system in an equitable, reliable, and cost-effective fashion, is critical. The increased demand arising from the affordable universal health coverage (UHC) initiative, changing epidemiological patterns and improved health education for Kenyans creates an even more compelling need for a functional HPT supply chain.

The National Pharmaceutical Policy, the overarching HPT supply chain policy, though developed before finalization of the Health Policy and the Health Act, 2017, recognizes the unique contribution of the HPT supply chain, not only towards improving health outcomes, but also to economic development. Recent review of implementation of national health sector strategy appreciated the existence and relevance of this policy, essential drugs lists, clinical guidelines and protocols, guidelines for various aspects for commodity management, public supply authority - a remarkable evidence that the Kenyan health sector has increasingly adopted and customized international instruments in the area of essential health products and technologies. Despite these gains, low implementation level regarding the health products and technologies policy stipulations has been recorded. In terms of accessibility, marginal improvements have been recorded with the average availability of essential medicines, and basic diagnostics standing at 41% and 45% respectively[2].

Various capacity building initiatives, mainly focusing on quantification, commodity management and the use of the Logistical Management Information System (LMIS), have been rolled by the Ministry of Health out over the last decade with the support of development and implementation partners. Facility ordering capacity, order fill rates, order turnaround time (TAT) have improved, but still below target and exhibiting inconsistencies and disparities. Distribution chain has also been strengthened on the back of infrastructural advancement and technology adoption. TAT for rural health facilities orders from KEMSA in 2016/2017, 2017/2018 and 2018/2019 were 10.3, 12.3 and 14.6 days respectively against a target of 10 days. Order fill rate for Essential Medicines and Medical Supplies (EMMS) for KEMSA in 2019 was 83% while for facilities it was 52% [3]. There is room for improving the supply chain through effective collaboration between public and private sectors.

Challenges regarding regulation, affordability of essential HPT in Kenya persist. Measures for strengthening availability and affordability of HPT, spearheaded by the government have included: improving the policy, regulatory and business environment; removal of import duty on imports of pharmaceuticals, provision of free or subsidized medicines through the public health facilities under cost sharing arrangements and the national strategic priority programs; and strengthening bulk procurement through KEMSA. However, cumulative evidence suggests that these measures have yet to produce equitable and pervasive effect in terms of availability and affordability desired for accelerated achievement of Universal Health Coverage.

2 MOH (2019). Kenya Harmonized Health Facility Assessment 2018/19

3 MOH (2019). Health Sector Working Group Report

Out of Pocket (OOP) expenditure on health as a proportion of total health expenditure is high (26.1)[4] with approximately 50%[5] estimated to be attributable to cost of medicines.

Efforts to revitalize local production of HPT with a view to improving accessibility, affordability and contributing to economic growth are notable, but have not had significant impact. Imports continue to grow faster than exports. The value of manufacture of basic pharmaceutical products and pharmaceutical preparations was KES 21 Billion in 2017, accounting for 1.7% of the manufacturing output for that period. Capacity utilization is estimated at between 40-60% and therefore there is still room for improving productivity. The local manufacturing industry for basic pharmaceutical products and pharmaceutical preparations had 5,744 employees in 2017[6].

Kenya has domesticated TRIPS Agreement flexibilities, envisaged under the Doha Declaration, in the Industrial Properties Act, 2011 but actual exploitation of the flexibilities has been limited save for parallel importation. On the research front, the Kenya Medical Research Institute has carried out varied research including pre-clinical studies for various herbal medicines for treatment of NCDs and contraceptives; and developed several rapid diagnostic tools. There remains a challenge in optimizing linkage between research on HPT and policy making. Traditional and Alternative Medicines agenda is now anchored on the omnibus Health Act, 2017 but operationalization through specific law and policy has been slow. Although pharmacovigilance and post-market surveillance policies are now in place, there are huge challenges regarding close monitoring and enforcement.

These HPT supply chain issues coupled with challenges of fragmentation in coordination of health commodities supply chain, necessitates the development of a focused HPT strategy to improve coordination, elaborate strategic directions and investments, and enhance decision-making.

1.4 STRATEGY DEVELOPMENT PROCESS

The Ministry of Health adopted a consultative and participatory process in the development of this strategic plan. It acknowledges the devolved system of governance in the country and the multiplicity of stakeholders involved in the management of health products and technologies and the attendant supply chain functions.

The first step was identification of the need and conceptualization in consultation with stakeholders. An elaborate road map that outlined the process of development including stakeholder engagement activities was developed. Additionally, a technical working group was established to coordinate the various activities with the support of the Division of Health Products and Technologies as the Secretariat. Financial and technical assistance was obtained from USAID through USAID funded Afya Ugavi program implemented by Chemonics Kenya.

4 MOH (2017). Kenya National Health Accounts 2015/2016.

5 MOH (2018). Kenya Household Health Expenditure and Utilization Survey, 2018

6 Kenya National Bureau of Statistics. 2020. Economic Survey 2020

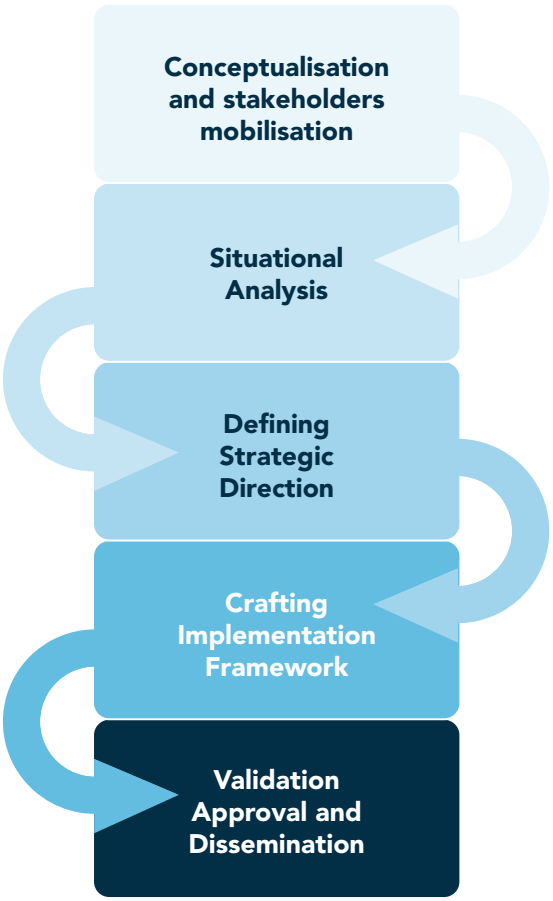


Figure 2 | Strategy Development Process

Situational analysis phase comprised of both desk review of published and grey literature, and key informant interviews. The desk review of policy documents, program assessment reports, program implementation reports, sector surveys and research reports, guidelines, standards, and statistical abstracts was carried on a thematic area basis. Ten thematic areas were identified on the basis of preliminary desk review as follows: common functional areas of supply chain – product selection, quantification, procurement, warehousing, distribution, waste management and rational use; cross cutting issues - policy governance and regulation; and enabling factors - human resources financing and resources mobilization, information management, monitoring, evaluation, and research. Identification of thematic areas was guided by the pharmaceutical management cycle that considers selection, procurement, distribution, use, management support and policy, law, and regulation[7]. Thematic areas review teams were constituted, and the review undertaken taking into consideration the various levels of the health services delivery system – national, county, health facilities and community - in terms of capacity and performance of the Health Products and technologies.

A desk review analysis report was generated highlighting the status of the landscape, challenges, priority areas of intervention and suggested strategic interventions. This analysis was corroborated with information obtained through key informants' interviews. Key informant interviews were carried out with stakeholders from both public and private sector. These activities happened during the time of COVID 19 restrictions and therefore application of technology for virtual meetings was a key leverage.

Following the generation of the situational analysis report, the strategic direction was defined in terms of the vision, mission, strategic pillars, and interventions. This exercise was undertaken through the thematic groups, then refined through consultative meetings with the technical working group and identified stakeholders from both the public and private sectors. A draft strategic plan was developed capturing the proposed strategic direction that was based on the consensus of the stakeholders. Further, refinement of the document was done in terms of the implementation plan, costing of interventions and performance framework. This document was then taken through, both internal validation with Ministerial leadership team and external validation with stakeholders.

7 Management Sciences for Health.2012. MDS-3-Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health.

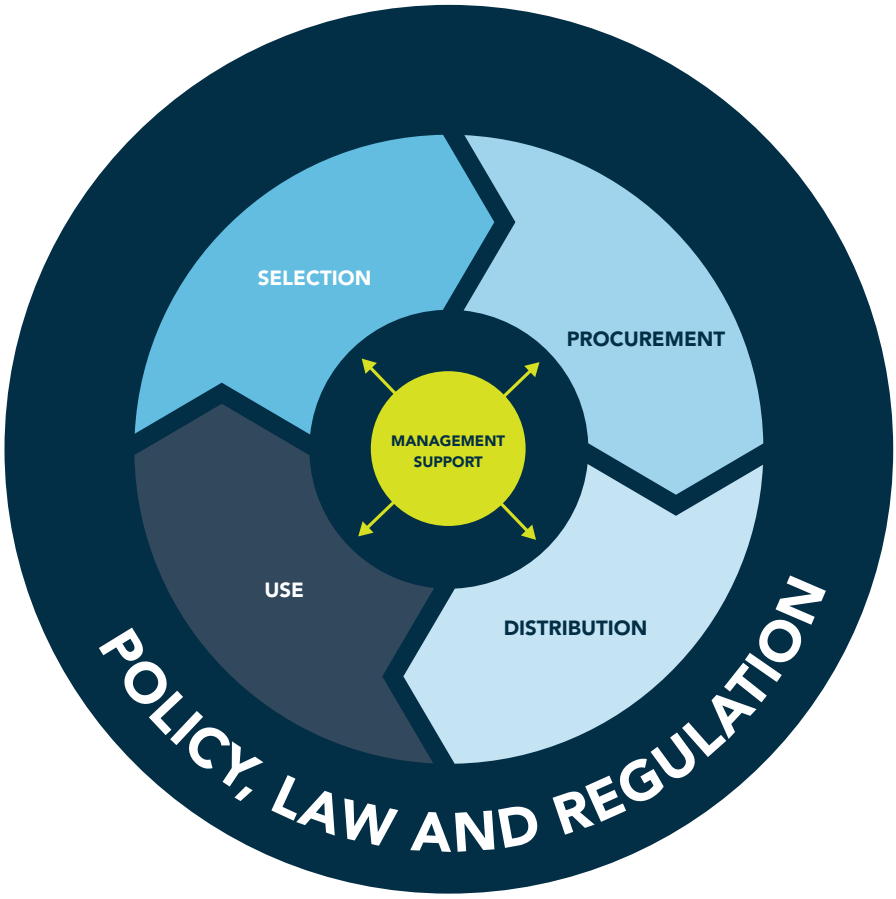


Figure 3 | *Pharmaceutical Management Cycle*
(Source: Adapted from MDS-3-Managing Access to Medicines and Health Technologies. Arlington, VA: Management Sciences for Health)

CHAPTER 1

CHAPTER 2:
SITUATIONAL ANALYSIS

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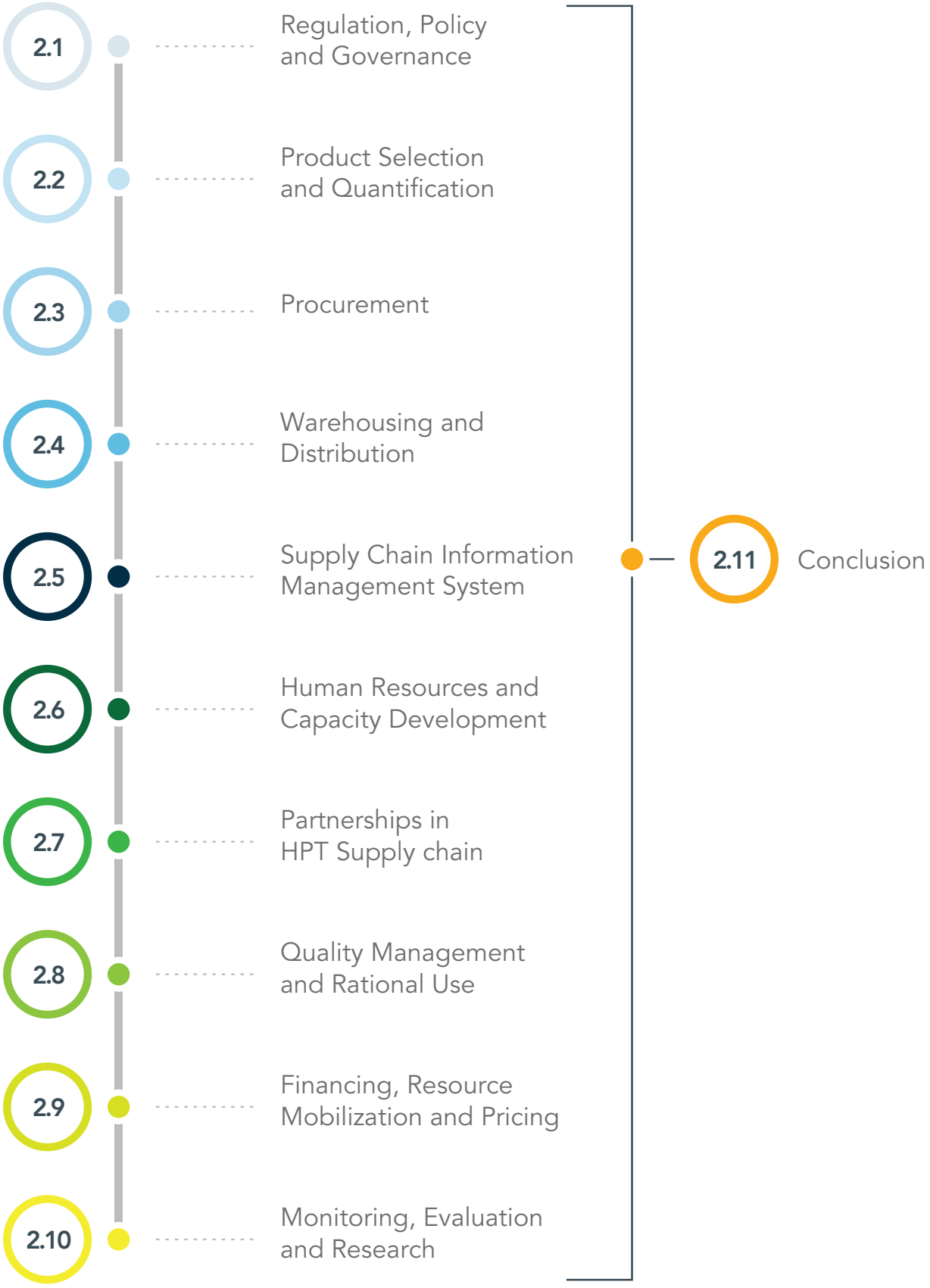
SITUATIONAL ANALYSIS



The situational analysis was conducted through thematic based desk reviews and corroborated with key informant interviews. The process enabled understanding of the current landscape of the health products and technologies (HPT) supply chain, appreciation of roles and expectations of the various stakeholders, identification of key challenges, priority areas for intervention, and possible strategic interventions. Further, the proposed strategic interventions and expected outcomes identified during the situational analysis guided the crafting of the strategic direction.

2.1 REGULATION, POLICY AND GOVERNANCE

2.1.1 HPT Supply Chain Policies

A review of the policy, legal and governance environment reveals that the improvement of procurement and availability of essential HPT is one of the priority reform areas for the health sector in Kenya Vision 2030. Scaling up of investment in HPT is one of the anchors for the achievement of the six health objectives/outcomes of the *Kenya Health Policy 2014-2030 (Sessional Paper 7 of 2012*), the overarching framework guiding the nation towards attainment of the highest standard in a manner that is responsive to the need of the population. *The Kenya National Pharmaceutical Policy (Sessional paper 4 of 2012)* is the overall guiding policy on HPT with the goal of achieving universal access to quality essential medicines, essential health technologies, and pharmaceutical services in Kenya. The implementation of this policy has been low [8]. Key achievements include harmonization of centralized procurement, warehousing, and distribution through KEMSA, formulation of essential HPT list and improved availability of essential HPT over the period. However, critical issues affecting the HPT supply chain identified then (2012), have persisted.

National Health Strategic Priority programs such as Malaria, HIV/AIDS, Non-Communicable Diseases, TB and Lung Diseases, and Immunization have a significant proportion of their budgets and activities dealing with HPT for prevention, diagnosis, and treatment. Strategies for achieving for these programs recognize the critical value of HPT investment.

A national pharmaceutical development strategy was developed to advance the agenda of promoting local production, research, and innovations of essential HPT. Its policy proposals are in line with the national industrialization policy, and regional and international efforts for increasing access to quality and affordable essential HPT (Africa Union Pharmaceutical Manufacturing Plan of Action - AU PMPA, East Africa Community Regional Pharmaceutical Manufacturing Plan of Action – EAC PMPA). Both the local production potential and the challenges faced by domestic manufacturers have also been articulated in various conferences and forums held in the region and the county.

2.1.2 Relevant Legislation

Significant efforts have been made towards enhancement and harmonization of legislative framework in support of HPT supply chain. *The Health Act, 2017* provides for the establishment of a body to regulate the licensing, manufacturing, laboratory testing and inspection, storage and distribution facilities, clinical trials, advertising and promotion, and post-market surveillance for quality safety and disposal of health products and technologies through an

8 MOH (2019). Draft Kenya Health Sector Strategic Plan 2018 – 2023

Act of Parliament. This expanded the classes of products covered to include therapeutic feeds and nutritional formulations. Additionally, the Act requires that procurement of HPT for public health services be undertaken in line with the Public Procurement and Disposal Act and agreed intergovernmental arrangements; KEMSA should also be considered as the first point of call for procurement of health products at the county referral level. The Act also makes a provision for the establishment of a regulatory body on the practice of traditional and alternative health practices, that shall set the minimum standards of practice and licensing for traditional medicine and alternative medicine in Kenya.

Nationally, the *Public Procurement and Asset Disposal (PPAD) Act No. 33 of 2015* guides procurement of HPT. The MOH procures medicines and commodities through KEMSA - mandated for procuring, warehousing, and distributing essential medicines and medical supplies in Kenya under the *KEMSA Act 2013*. Management of the health commodities largely follows the *Pharmacy and Poisons Act Cap 244* and other relevant legislation. Procurement is also guided by rules and regulations of donor agencies and other relevant organizations in the case of special/priority programs. Other legislations applied in management of HPT supply chain include the *Public Financial Management Act, 2012* and *County Government Act, 2012*. State agencies such as KEMSA, PPB, NQCL and academic institutions are also governed under the *State Corporations Act, Cap 446*.

Progress has been made in delinking regulation from pharmaceutical policy making and sector administration. The KNPP envisages a restructured regulatory environment with PPB and NQCL granted more autonomy, and PPB restructured to Food and Drug Authority (FDA). A draft FDA Bill No. 31 of 2019 was introduced in parliament in April 2019 as a private members' bill and subjected to first reading in May 2019. However, the introduction received a lot of opposition from stakeholders, especially the lack of regulatory environment impact assessment bearing in mind that it proposes repeal of the *Pharmacy and Poisons Act Cap 244*, *Food and Drugs and Scheduled Substances Act Cap 254* and sections 16, 17 and 18 of the No. 14 of 1994 Narcotic Drugs and Psychotropic Substances; in addition to a raft of institutional framework changes.

In 2019, several health-related laws were amended through an omnibus Health Laws (Amendment) Act, No. 5 of 2019. *KEMSA Act, 2013* was amended to provide for county representation in the board and enhance governance structures; KEMSA was also designated as the sole procurement agent of HPT for all public facilities. Several changes to the Pharmacy and Poisons Act made through *The Health Laws (Amendment) Act*, No.5 of 2019 are aimed at increasing the autonomy of the board and strengthening its regulatory capacity for both HPT and professionals. Although the impact of these changes is yet to be assessed and documented, there are prevailing challenges with KEMSA's ability to respond to increased demand for HPT from public facilities. There have been incidences of inadequate coordination by regulatory bodies – Pharmacy and Poisons Board (PPB), Medical Laboratory Technologists Board (MLTB), National Quality Control Laboratory (NQCL), and Kenya Bureau of Standards (KEBS) – leading to inefficiencies in some of the HPT Supply Chain functions such as quality testing, quantification and planning, and procurement.

Regulatory inadequacies have also contributed to product quality risks in the private sector. This situation is aggravated by the weak self-regulation capacity of the private sector. Further, there are gaps in enforcement of some policies such as the ones for generic prescribing

and adherence to essential HPT lists that are attributable to inadequacies in the regulatory framework.

2.1.3 Governance Arrangements

The Ministry of Health continues to provide stewardship over HPT supply chain in line with the Kenya Health Policy and Health Act, 2017. At the apex level, HPT Inter-Agency Coordination Committee (ICC) has been set up as part of the coordination structures encapsulated in the Health Sector Partnership Framework. The Framework outlines how the Ministry of Health, county governments, external and non-state partners should interact with each other. The ICC is meant to provide oversight on matters HPT and should meet on a quarterly basis. However, it is still inactive. There is a general acceptance amongst stakeholders that the stewardship effectiveness by MOH on HPT supply chain has fluctuated post devolution, with the earlier years having some transitional challenges but recent years showing restoration efforts. Various HPT Supply chain guidelines and tools have been developed recently but have yet to be widely disseminated. Additionally, there are ongoing efforts to streamline the oversight roles of MOH and KEMSA through formulation of a Memorandum of Understanding.

Notably, in 2019, the MOH elevated the HPT coordination function from a unit to a division under the department of health systems strengthening in the directorate of healthcare services with a ten-items mandate cutting across policy, standards, regulation, coordination and capacity building. The division's capacity in terms of staffing, equipment, and budget to deliver this mandate is inadequate. However, there are initiatives under consideration to scale up the division's capacity through collaborative support between MOH and partners. At the national level, KEMSA, PPB, NQCL, KEMRI and NHIF have defined their strategic direction through current and ambitious strategic plans covering part of the period targeted by this strategic plan. This review noted that there is a need to complete and launch strategic plans for KEMSA and NQCL to enhance awareness, ownership, and improve on accountability. Other concerns identified with respect to the strategies include the following: clarification of proposed ICT strategies in line with overall direction of the ministry; harmonization of investments in equipment and infrastructure relating to warehousing, distribution, quality control and testing functions for HPT supply chain; alignment to proposed financing mechanisms involving pooling and with enhanced role of NHIF.

With devolved governance taking root, the overall governance structures for health service delivery for county governments have been established and rationalized. At county level, the health sector is headed by a County Executive Committee Member for Health, who is supported by a Chief Officer for Health who is the accounting officer. The County Director for Health oversees the technical aspects of the health sector and heads the county health management team. Most counties have designated members of CHMT, domiciled in the departments of health, to coordinate health products and technologies (HPT) functions in collaboration with the county supply chain units that are mostly centralized. In line with the *Public Financial Management Act, 2012*, the supply chain directorates for county governments, through the County Treasuries are responsible for development of consolidated county government procurement plans and quarterly reporting on implementation.

County governments do have commodity security working group designed alongside the parallel priority programs for HIV/AIDS, Malaria, TB, and Immunization. However, only one (out of 47) county government has an established County Medicines and Therapeutics Committee. Several hospitals have active Medicines and Therapeutics Committees. As a result, there is fragmentation in handling of HPT supply chain functions and attendant inefficiencies during quantification, procurement, warehousing, and distribution. Focus on HPT at intergovernmental relations level is still a challenge as the HPT ICC is still at its infancy. Communication on HPT policies and strategies has also been sub-optimal as noted during HPT procurement planning and budgeting in support of roll out of affordable UHC. Delays in streamlining such processes could lead to displacement of budgets for HPT especially for county governments.

Implementation of various policies has been stifled by lack of clarity over roles, inadequate public participation, failure to position the unique aspects of HPT, fragmentation in the private sector in view of the large number of providers, inadequate organizational capacity of the regulator, inadequate coordination between key public agencies – ministries responsible for Treasury, Industrialization and Trade, and Health as well as regulatory agencies – on some policy issues for HPT.

2.2 PRODUCT SELECTION AND QUANTIFICATION

2.2.1 Product Selection

The Kenya Essential Medicines List (KEML), Kenya Essential Medical Supplies List, and Kenya Essential Medical Laboratory Commodities List (KEMLCL) were previously updated in 2016. There was an ongoing update at the time of developing this strategy. Stakeholders acknowledge that the lists are considered in product selection but there are disparities in application of essential lists both in public and private sectors, and that inadequate feedback is obtained and processed on the essential lists. It is notable that KEMSA has applied the essential list for EMMS to a great extent in its product selection.

Standard Treatment Guidelines available were developed in 2009 and are now deemed out of date. There are no reliable surveys undertaken on the extent of application of the standard treatment guidelines and protocols, and thus, the identified need for studies on adherence.

2.2.2 Quantification and Forecasting

PRIORITY GAPS

- Inadequate application of Standards Treatment Guidelines
- Inadequacies in coordination for forecasting and quantification at national, program, county and facility levels
- Fragmentation of capacity building initiatives on quantification of HPT
- Weak linkage between quantification plans, procurement plans, and annual budgets
- Inadequacies in availability of high quality national, county and facility data on consumption, stocks and service demand to support quantifications
- Inadequate capacity in terms of human resources, tools, and skills for product selection and quantification
- Failure to fully utilize the supply plans resulting from quantification exercises to inform actual procurements

All stakeholders acknowledge the importance of effective quantification, as a core element and anchor for other HPT supply chain functions. Further, the complexity in quantifying and forecasting HPT needs at national, program, county and even facility level is also widely appreciated. Admittedly, there have been various initiatives, mostly supported by development and implementation partners, to improve capacity in quantification and forecasting for HPT with a concentration on the priority national programs – HIV/AIDS, Malaria, TB, Vaccines and RMNCAH. For these programs, there has been progressive improvement in quantification including consideration of epidemiological data, service data sets, logistical data as well as skills building. The programs have developed supplementary guidelines for instance the immunization management guidelines and performance management handbook. For most of the other HPT, quantification is based on consumption data.

Accuracy and reliability of quantification outputs remains a challenge. For instance, KEMSA's accuracy for demand forecasting is estimated at 59% against a target of 95%. In terms of application of essential lists, 73% of pharmaceuticals and 94% of non-pharmaceuticals in KEMSA's warehouse commodities are on the Kenya's KEML and KEMSL lists[9]. County governments capacity for quantification of HPT is also inadequate - only 23% (11 out of 47) counties undertook adequate quantification for UHC, ahead of the UHC program scale up. The linkage between HPT quantification outputs, procurement plans and annual budget estimates is weak, leading to huge variances between what is quantified and what is ultimately made available. A cursory review of HPT quantification reports from nine counties (Homa Bay, Kilifi, Lamu, Mandera, Marsabit, Migori, Nairobi,
Samburu, and Tana River) indicated that the average fulfilment of HPT requirements based on quantifications was at 46% for public facilities. These eminent gaps in quantification of HPT and the resulting overestimation or underestimation contribute significantly to expiries, stock outs, unnecessary costs, and health service disruptions.

There have been recent efforts by the Ministry of Health in improving capacity and coordination in quantification and product selection, such as: development of guidelines for forecasting and quantification and a roadmap for building capacity of county health management teams in quantification of HPT. Whilst these measures are taking effect regarding essential medicines, the pace of progress is slow with essential medical supplies and medical devices. Even with the guidelines, availability of high quality national and county data on consumption, available stocks and service statistics still poses a challenge

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in accuracy and reliability of quantification estimates for HPT at all levels, resulting in supply plans not informing actual procurements that are undertaken.

2.3 PROCUREMENT

2.3.1 Procurement law, policies, and procedures

Public sector procurement in Kenya is governed by the *Public Procurement and Assets Disposal Act, 2015* and PPAD Regulations of 2020. Additional important legislation that is relevant for procurement of HPT include: *The Public Finance Management Act, 2012; The Intergovernmental Relations Act, 2012; The County Government Act, 2012; KEMSA Act, 2013; Pharmacy and Poisons Act, Cap 244; and the Health Act, 2017*. Regulation of public procurement of HPT is handled by the Public Procurement Regulatory Authority and the Public Procurement Administrative Review Board with the Pharmacy and Poisons Board handling the quality aspects. The Kenya Health Policy requires the national government to acquire and maintain adequate stocks of the strategic and special/expensive categories of products whilst county governments focus on ensuring availability of essential/basic products at county health facilities in accordance with the essential lists for HPT.

The Health Act, 2017 requires the national government to provide guidelines for the procurement, distribution and management of health products and technologies including essential medicines, laboratory chemicals and reagents and non-pharmaceuticals at all levels of the national health system. Towards this end, the Ministry of Health has developed draft guidelines that await validation, approval, and dissemination. There exists a public procurement manual for health sector that was developed by Public Procurement Regulatory Authority in 2009 but was not disseminated and therefore its application is in doubt. These guidelines, and others, documented through standard operating procedures (SOPs) for large agencies that have achieved ISO certification, complement the PPAD Act 2015 and its regulations.

For the public sector, the responsibility of ensuring compliance with procurement laws for public entities (procuring entities) is vested in accounting officers of national and county governments. Accounting officers make decisions on tender decisions taking into consideration the professional views of the heads of supply chain management. County governments have devolved the accounting officers' roles to the departmental level and not yet to sub counties and health facilities. There is room for decentralizing these roles bearing in mind that large health facilities were procurement entities prior to devolution. The required procurement and asset disposal committees (tender opening, evaluation, inspection and acceptance and disposal) as detailed in the PPAD Act, 2015 have been established and are functional at both national and county governments. Required procurement thresholds are observed too.

2.3.2 Procurement reviews and audits

Several procurement audits and reviews have been carried out on the HPT supply chain system over the last decade. Significant assessments have been undertaken by development partners such as the Global Fund, USAID, World Bank, GAVI and GIZ; the EACC and the OAG. These audits have tended to be ad hoc, with majority of them focusing on KEMSA. The reviews and audits have generated recommendations that have been instrumental in the strengthening of the HPT supply chain environment. Some of the most recent reviews, in addition to the annual audits undertaken by OAG, include: a joint assessment of KEMSA by the Global Fund and USAID; EACC Assessment of Affordability of HPT; Global Fund Assessment of the laboratory supply chain.

An Essential Vaccines Management (EVMA) assessing the effectiveness of the vaccines supply chain was underway at the time of the review - following the previous one in 2013.

PRIORITY GAPS

- Inadequate use of information systems for monitoring the extent to which procurements follow established norms and procedures, especially regarding quality, managing supplier performance and in collecting pricing data
- Contract management challenges at both national and county and facility levels
- Delayed amendments to the PPAD Act 2015 Regulations and harmonization with the Supplies Practitioners Management Act, 2007 and KEMSA Procurement Policy

These reviews reveal significant gaps in procurement planning, contract management, sharing of information, vendor performance management, insufficient competition for procurement of services, unintegrated procurement planning, and unclear criteria for splitting awards between vendors.

2.3.3 Procurement planning

Public entities are required to prepare their procurement plans in conformity with the medium-term fiscal framework and fiscal policy objectives. The plans are expected to integrate reservations and preference aspects, and multiyear procurements where necessary. Therefore, procurement plans, that are placed as a responsibility for accounting officers, are aligned to the planning and budgeting cycle. These outputs are submitted to Treasury within 60 days of commencement of the fiscal year and reporting on their implementation is done on a quarterly basis to the Public Procurement Regulatory Authority. Although requirements are generally adhered to, the extent to which the quantification plans for HPT inform the procurement plans is limited for the government funded procurements whose funding goes through the consolidated fund and the county revenue fund.

PRIORITY GAPS

- Fragmentation in procurement with KEMSA not yet undertaking procurement of some HPTs medical equipment
- Inadequate mechanisms for ensuring access to EMMS through non-public providers, including alternate sourcing facilities in the event of stock-outs at KEMSA
- Inadequate mechanisms for the procurement of medicines for emergencies
- Inadequate collaboration between private sector and public sector (lack of leveraging of each other's capacity and expertise)
- Unintegrated procurement planning, procurement, and information management system of various commodity categories thus causing inefficiencies and stifles accountability

The MOH procurement planning and procurement processes run vertically by individual strategic health programs (HIV, TB, Malaria, Vaccines, RH/FP) and EMMS; while commodities for other essential support services such as laboratory and radiology are not as clearly defined. Consequently, procurement planning and information systems are not integrated at either KEMSA or MOH level. KEMSA does not have a consolidated procurement plan and thus procurement is fragmented along health programs and funding streams resulting to inefficiencies on investments. With roll out of UHC and new regulatory requirements for all public facilities to procure exclusively from KEMSA, this presents further risks of stock outages and wastages. It is important to note that county governments and public health facilities are required to procure HPT from KEMSA in line with the new requirements under the Health Laws (Amendment) Act, 2019. Essentially, procurement outside KEMSA would require counties to get exemptions from KEMSA but there is no clarity on the direction of this new requirement thus posing risks of noncompliance and penalties; and shortages with regards to products that KEMSA may not have.

Other inefficiencies experienced in the HPT supply chain procurement process are attributable to inconsistencies in administrative and approval processes. These include delays in clearing of imports, delays in securing import permits from the Pharmacy and Poisons Board (PPB) and tax exemptions from the National Treasury and Kenya Revenue Authority (KRA) as well as requirement for Pre-Shipment Verification of Conformity (PVoC) by the Kenya Bureau of Standards. Delays in clearance has also characterized commodities that are procured against official grants which provide for Tax Exemption.

Procurement of HPT is significantly dependent on external donor support. Key contributors to the HPT national budget, other than government include the USAID, the Global Fund, the World Bank, GAVI, DANIDA, and the DFID. For instance, USAID/KEA has significant current grants towards strengthening KEMSA's internal systems as well as procurement of HPT. Similarly, the Global Fund has active multi-year grants in support to HIV, TB, and Malaria programs, of which approximately 60% goes to HPT SC[10].

Global Alliance for Vaccines and Immunisation (GAVI) provides funding for vaccines that are procured through the United Nations Children's Fund (UNICEF) that procures Kenya Expanded Programme on Immunization (KEPI) vaccines on behalf of the country. As such, there are also requirements to comply with procurement plans and procedures prescribed by these partners.

2.3.4 Product specification

In Kenya, pharmaceuticals, including specifications are highly regulated. All pharmaceuticals offered by the private sector (manufacturers, distributors, wholesalers, and retail chemists) are registered by the Pharmacy and Poisons Board after certification that they comply with international pharmacopoeia standards. However, there are numerous gaps in the specifications for medical and diagnostic supplies. This has affected the quality of products. There are more complaints about sub-standard quality for medical supplies and diagnostic products than there are for pharmaceutical products.

10 USAID (2019). Joint Assessment of KEMSA by the Global Fund and USAID

To ensure effective implementation of Universal Health Coverage, the MOH's Division of Health Products and Technologies has developed specifications for essential medical supplies and diagnostic supplies covering over 900 products[11].

2.3.5 Identification of suppliers

PRIORITY GAPS

- Numerous gaps in the specifications for medical and diagnostic supplies
- Sub-standard quality for medical supplies and diagnostic products
- Lack of reliable market surveys for HPTs as price lists provided by PPRA from are not deemed a reliable reference
- Failure to operationalize multiple awards regulation
- Inadequate supplier performance monitoring system during and post-performance thus jeopardizing supplier development as well as credibility of evaluations
- Inadequate capacity in ICT infrastructure, systems and skills to support HPT procurement planning and procurement across all levels

The process for the identification of suppliers in public sector procurement is detailed in the Public Procurement and Asset Disposal Regulations and the procurement manual of health commodities. Identification of suppliers is a continuous process. The PPAD Act, 2015 requires procuring entities to maintain an updated list of registered suppliers. KEMSA has a list of registered suppliers on its website. However, this list has not been updated for the FY 2020/21. No public listing of HPT suppliers is available on the MOH website or county government websites. Maintenance of vendor information in the public sector is largely manual, even at KEMSA which has an enterprise resource planning system for managing other aspects of the supply chain. In the case of vaccines, UNICEF as the procurement agent undertakes international sourcing informed by specifications developed by the MOH through the National Vaccines and Immunization Program (NVIP).

KEMSA has an established system for sharing information with vendors and potential vendors on procurement process. Bid conferences are held as part of its procurement process and summary of contract awards posted on its website. No such system is available at the Ministry of Health. County governments have also applied these requirements inconsistently. Whereas information on bids is available, there is no available documentation on solicitation schedules which tend to be erratic. Information on the management of proprietary information for bidders/vendors is also not available.

The private sector remains the most significant source and supplier for HPT to the public sector and the nation at large. However, the private sector is fragmented with many small manufacturers importers, distributors and retailers leading to inefficiencies, high prices and HPT quality issues. Application of negotiated framework contracts and pooling mechanism is not common thus opportunities for improving quality and reducing prices are not exploited adequately. This is aggravated by the lack of transparency in procurement in the private sector.

In the private sector, identification of suppliers is done through active sales and marketing activities by the suppliers themselves and passively through various online channels. The private sector does not share information on its procurement process. This can partly be attributed to unavailable law that compels them to do so.

11 MOH (2020). Draft Essential Lists for Medical Supplies and Diagnostic Supplies

2.3.6 Tendering

The management of the tendering process in the public sector is largely manual, with standard tender documents applied. KEMSA tender documents have been further customised to reflect unique aspects of HPT procurement including quality assurance and evaluation criteria.

The HPT Tender award decisions are mainly based on cost and quality. Even though PPRA conducts routine market price surveys, there is no evidence on the application of market price indices and benchmarking by procuring entities. Appeal processes for procurement in the public sector are well defined and entities are fully aware of them. It is notable that dispute resolution for HPT procurements is prioritised in the judicial system. Although the PPAD Act, 2015 Section (4) allows for multiple awards for one commodity, its operationalization through regulations has not been effected limiting KEMSA in awarding multiple contracts for different suppliers for the same product, increasing the risks of stock outage and stifling competition.

Procurement processes in the private sector is much simpler than in the public sector even in organizations such as MEDS that use the tender system. This is attributable to faster decision-making and the absence of the statutory periods in the various procurement stages that characterise the public procurement system. MEDS mainly applies a closed system of prequalified suppliers and has made good progress in applying multiple awards for critical items and application of technology to manage the procurement process. There are opportunities for cross learning and knowledge exchange between KEMSA and MEDS. For international sourcing, there is reliance on the WHO guidelines on procurement of prequalified vaccines in addition to the local requirements for registration.

2.3.7 Management of vendor performance

The system of managing vendor performance in the HPT supply chain is more established in private sector entities that the public sector. Large public sector procuring entities such as MOH, county governments, national referral facilities and KEMSA have suppliers' previous performance as an evaluation criterion, however, this has tended to be more transactional than strategic as a result, the sector suffers from late deliveries, poor supplier fill rates, unsatisfactory responsiveness, poor quality and inadequate risk management. Whereas value for money is one of the procurement principles in the Public Financial Management Act, 2012, there is limited measurement and monitoring to ensure it is attained.

The current strategic plan for KEMSA identifies poor supplier performance as one of its highest enterprise risks and prioritises contract management as a strategy to manage this risk. MEDS also does acknowledge importance of managing supplier performance and holds an annual suppliers conference as part of its supplier development program. There are opportunities for these bulk purchasing agents to strengthen their programs for building relationships with suppliers leveraging on their enterprise resource planning systems.

At the national level, procuring entities contract terms include delivery to the warehouse of point of use in the case of large equipment. The Pharmacy and Poisons Board has developed and rolled out Good Pharmaceutical Distribution practices that include importation

procedures. The procedures include issuance of import permits by the board and physical inspection of all pharmaceutical imports. However, no such systems are in existence for KEBS and the KMLTTB for medical supplies and diagnostic supplies, respectively.

Increasingly, ICT systems are being applied to support HPT procurement in the public sector. The national government ministries and agencies utilize the e-procurement module in the IFMIS system, but county governments are yet to fully utilize it owing to various challenges such as inadequate skills by users, poor IT infrastructure, lack of internet bundles and frequent down time of the system. There is inadequate capacity in ICT infrastructure, systems, and skills to support HPT procurement planning and procurement across all levels.

In terms of performance in procurement of HPT, order fill rate for EMMS by KEMSA stood at 52% in FY17/18 as per the Kenya Health Facility Assessment (KHFA), KEMSA's order turnaround time for hospitals is 15 days against target of 5 days, while for rural health facilities (RHFs) was 15 days against a target of 8 days. The average availability of basic diagnostic tracer items and EMMS in PHC facilities was 45% and 41% respectively. The Kenya Health Facility Assessment (KHFA) also revealed that the Percentage of Health facilities with stock out for any of the 18 tracer medicines for 7 consecutive days in a month was 44% in FY 17/18.

PRIORITY GAPS

- Lack of clarity in terms of chain of custody when HPT move from KEMSA and are received at the lower level facilities of county governments
- Sub-optimal use of technology
- Weak monitoring and supervision systems
- Reliance on donors for infrastructural and systems improvements
- Poor enforcement of standards due to weak oversight systems
- Limited storage space at county and facility level
- Unavailability/use of stores management tools
- Skills gaps in warehousing and inventory management
- Stock out of HPTs items health facilities at times when KEMSA holds large stocks of the same
- Product unavailability at lower levels (county and health facilities)
- LMIS lack real time visibility of KEMSA stock levels by facilities and in transit
- KEMSA has weak order scheduling from the counties for non-program items
- Sub-optimal collaboration between public, private and faith-based systems
- Low enforcement of good distribution practice guidelines
- Last mile delivery not happening for all HPTs especially program ones
- Significant delays for orders that are not scheduled
- Stand-alone distribution of program orders not sustainable
- Increasing discrepancy amongst third party transporters
- Inadequate structures for inter- and intra-county distribution and reverse logistics of obsolete, excesses or for disposal items
- Inequity in distribution of waste disposal sites in the country
- Dysfunctional waste disposal sites
- Guidelines for disposal of HPT waste not yet disseminated

2.4 WAREHOUSING AND DISTRIBUTION

2.4.1 Warehousing and distribution

KEMSA has strong SOPs and operations capacity developed over years of investments. Various assessments conducted over the last decade (including one in late 2019) have facilitated identification of gaps and planning for capacity building. KEMSA employs a pull model, where deliveries are based on demand, for most regions. As the established sole supplier for the entire public sector, KEMSA has nationwide storage of medicines and health products, with four warehouses in Nairobi and eight regional depots in Mombasa, Kisumu, Nyeri, Nakuru, Garissa, Meru, Eldoret and Kakamega. KEMSA's eight 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. KEMSA has a warehouse management system (WMS) that is integrated with order system. The WMS has defined inventory levels.

However, unpredictable demand and undefined ordering cycles sometimes leads to periodic overstocking and resultant overcrowding at warehouses. Instances of ordering annual quantities, to avoid delays in customs clearance have also resulted to high inventory levels and increased risk of expiries.

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.

Mission for Essential Drugs and Supplies (MEDS) is another large-scale, bulk procurer of medicines and health products. 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 organization provides services

to over 1,820 health facilities but also offers capacity building programs for health workers, quality control, and other pharmaceutical services.

KEMSA and MEDS have a large national footprint reaching both public and private entities. KEMSA is the main distributor of prescribed public health programs, the national strategic stock reserve, prescribed essential health packages and national referral hospitals. KEMSA, MEDS, and other private entities engage private 3PL (third party logistic) firms to reach facilities across the country. However, the private sector is heavily skewed towards urban centres.

With regards to vaccines, the regional depots of KEMSA are utilized, in addition to stand-alone depots in Meru, Kakamega and Garissa. Special vaccines such as Hepatitis B are stored at the National depot in Kitengela. UNICEF undertakes distribution up to the regional depots from where county governments collect, on quarterly basis. Private facilities pick the regular KEPI vaccines from the sub-county depots. Moveable cold rooms exist at the depots. The storage facilities at national, regional, and sub-county level are deemed adequate. However, at facility level, they are inadequate.

The regulator has provided adequate guidance on distribution and transportation practices to support the HPT supply chain. Guidelines for good distribution practices issued by PPB in 2019 highlight structures (fixed structures/premises), function, roles, responsibilities, and requirements for all players at different levels and required documentation. Guidelines for transportation of pharmaceuticals issued in July 2019 are also deemed as adequate.

KEMSA undertakes distribution from national level to health facilities (doorstep distribution for EMMS) under the last mile initiative pilot. Distribution to central sites, sub-county stores happens for program HPT. Inter- and intra-county distribution is undertaken for excess HPT while reverse logistics for disposal of some program HPT happens but in a fragmented fashion. GPS tracking is used by KEMSA and MEDS for tracking distribution tracks. The internal processes for quality control have been rated highly with pass rates above 98% (approximately 85% of customer are satisfied with quality)[12].

2.4.2 Waste Management

Waste management guidelines exist in draft form (2019) but have not been disseminated and applied. Responsibilities for waste management are coordinated by PPB, NEMA and MOH (Public Health). Significant disparities exist in waste management capacity across counties and levels of healthcare system.

The MOH undertook mapping and documentation of waste disposal sites in the country in 2018. The documentation was done as part of development of the Kenya Emergency Supply Chain Framework to eliminate the need to transport hazardous waste over long distances and ensure that sites get only the waste they can adequately dispose.

The documented waste disposal sites that fall under the MOH and County Governments are as follows: Wajir County Referral Hospital (CRH), Kitale CRH, Busia CRH, Voi CRH, Makindu County Hospital, Eldama Ravine County Hospital, Isiolo CRH, Maragua County Hospital,

12 KEMSA Annual Report 2018 & 2019 and MEDS Annual Report for 2018

Embu CRH, Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), Mombasa CRH, Nyeri CRH, Nakuru CRH. These sites have capacity of between 50 – 100 kg/hr.

The private disposal sites include:

a) E.C.C.L located in Stoni Athi and Migori County
b) Envirosafe Ltd in Athi-River EPZ Machakos
c) Green City, Embakasi, Nairobi
d) Usafiplus Waste Disposal Services Enterprise Rd, Nairobi
e) Tranzbiz Hazardous Wastes Solutions, Ruiru Kiambu
f) Bamburi Cement Mombasa County.

Waste management in the sub-national facilities has improved with entrenching utilization of colour coded waste bins and disposal bags, as well as increased use of burning chamber/ incinerator or other working arrangement with nearby facilities for incineration. Although attempts have been made to coordinate the utilization of network of available facilities, disposal of waste has not been undertaken effectively and efficiently. Significant waste management activities happen at facilities and the capacity varies across the country. Other issues identified include: delays in disposal of expired products, design issues affecting disposal of liquid waste, inadequacies in waste management infrastructure such as incinerators and safety tanks, sub-optimal destruction of hazardous waste, insufficient protective equipment for the staff, inadequate numbers of waste bins and disposal bags.

2.5 SUPPLY CHAIN INFORMATION MANAGEMENT SYSTEM

Over the last five years, the health sector led by the MOH has formulated sectoral guidance on health information system, including the management information system for HPT. However, the guidance needs to be updated to reflect the legal requirements of the Data Act, 2019, and disseminated. There is significant fragmentation in the information systems currently used to support the HPT supply chain system. Though Logistics Management Information System (LMIS) designs exist for some HPT, they are not integrated and do not function adequately. Besides the lack of interoperability and limited integration, the following challenges exist; data collection and sharing are inadequate; data visibility is limited at all levels of the supply chain and incomplete reporting is experienced.

In terms of systems in application, inventory management at KEMSA is fully electronic but at public health facilities both electronic and paper systems are applied. KEMSA LMIS is limited in handling only ordering of commodities from the service delivery points (SDPs). KEMSA's ERP supports procurement, product selection, inventory management, reverse logistics but not forecasting, redistribution and waste management. It is apparent that significant investments have been made in strengthening the electronic order processing tools and components. Priority program commodities are at higher maturity level than the other EMMS in terms of order processing as consumption data is more closely monitored. Counties are at different stages in terms of ICT infrastructure and human resources management and the capacity to manage the LMIS. There is also inadequate ICT support and infrastructure for HPT at central, county and facility levels, and inadequate reporting tools and right version of tools.

Generation, collation, management, and utilization of data from the information system regarding HPT consumption and stock levels remains a big challenge. There are also notable challenges with data accuracy, timeliness and quality thus jeopardizing the effective HPT supply chain planning and decision-making at all levels. There is inadequate information sharing across the various systems – KHIS (DHIS 2), KEMSA LMIS and EMRs. Reporting by programs is still in silos with programs such as laboratory, nutrition, and vaccines limiting access to data. Additionally, reporting demands overwhelm facility health workers owing to the number of reports required.

There is poor record keeping practice from Daily Activity Registers, Bin Cards leading to submission of inaccurate summary data. This is aggravated by the irregular data quality audits. Data visibility across the HPT supply chain, especially from facilities, is also a significant challenge. Lack of visibility on stocks held at the facilities results in inappropriate stock holding within county as there is no easy way for health workers to visualize or analyze the data submitted monthly in the national system. There is need for commodity-based dashboards to inform redistribution and stocking levels.

2.6 HUMAN RESOURCES AND CAPACITY DEVELOPMENT

2.6.1 Staffing

In the public sector, human resource management is governed by the Public Service Commission Act, 2017 in terms of appointments, and transfers of staff. The state corporations such as KEMSA, Regulatory Boards and some national referral facilities are governed by the SCAC under the State Corporations Act. County government staff are governed by the County Government Act, 2012 that include provisions on the County Public Service Boards (CPSB). The Public Service Commission and CPSBs human resources manuals and SOPs are the key guiding documents for the public sector.

In terms of strategic guidance, the Ministry of Health has developed a Human Resource for Health Strategy (2019-2023) and is currently working on a health workforce accounts. The strategy envisions a re-engineered health workforce responsive to the universal health coverage agenda and particularly emphasizes health workforce capability building and better use of HRH databases to inform decisions. As per the strategy, a total of 148,322 health workers were in force in both public and private sectors in 2018. Of these staff, 68% were retained with the remaining 32% indicated as non-tracked. In terms of proportions of staff by major cadres, nurses accounted for 54.6%, clinical officers for 13.9%, pharmacy staff for 8.4%, medical officers and specialists for 7.9%, and laboratory staff for 7.81%. Pharmacy staff (pharmacists, pharmaceutical technologists, and drug inspectors) totalled 12,392 with the majority 6,061 (48.9%) in private sector, 2,016 (16.3%) in public sector and 4,315 (34.8%) not trackable. The un-trackable gap is attributable to attrition, slow absorption into service, practicing invalidity and apathy in renewal of licenses.

There are evident disparities in distribution of health workers including HPT supply chain staff. For instance, the top five counties with the highest ratio of pharmacists from non-government sector per 10,000 populations are Nairobi (1.9), Laikipia (1.3), Mombasa (1.0), Lamu (0.7), Kisumu, and Embu (0.6). Nairobi has the highest ratio of pharmaceutical

technologists to its population, i.e. 3.6 technologists per 10,000, followed by Mombasa (3.0), Uasin Gishu (2.8), Kiambu (3.9), and Kajiado (2.5).[13]

PRIORITY GAPS

- Overlapping and duplications in roles regarding HPT supply chain leading to inefficiencies and omissions
- Lack of clear formal supervisory relationships for some functions such as regional vaccines depots
- Inadequacies in HRH for HPT supply chain functions
- Inequity in distribution of existing staff
- High attrition of staff
- Productivity issues owing to inadequate supervision
- Schemes of service for several cadres who handle HPTs in practice do not reflect the responsibilities in practice
- Fragmentation in coordination and delivery of capacity building initiatives for HPT supply chain
- Inadequate tracking of trainees in HPT supply chain
- Lack of a comprehensive course on HPT supply chain management for health facilities in Kenya

2.6.2 Job descriptions

Most of the supply chain functions for HPT at central level and county level are performed by pharmacists and pharmaceutical technologists. At the service delivery points/ health facilities, the supply chain management functions for HPT are performed by Pharmacists Pharmaceutical Technologists, nurses, clinical officers and medical laboratory technologists. Functions related to procurement and procurement planning are performed by procurement or supply chain officers and supplies officers.

HPT supply chain functions within the public health priority programs are also carried by different cadres of staff, but each of the programs does have pharmacists and pharmaceutical technologists assigned to them. Each of the parallel programs – HIV/AIDS, Malaria, TB & Leprosy, Vaccines, Reproductive health has at least one pharmacist and one Pharmaceutical Technologist. All county governments have a pharmacist(s) coordinating HPT supply chain functions with the procurement roles undertaken by the heads of supply chain/procurement officers. The major roles for the pharmacists in this case is receipt of facility data and quality assurance reporting, but the pharmacists at facilities do coordinate dispensing of HPT. Most lower level facilities (Level 2 and 3) are manned by clinical officers and nurses who also fulfil the HPT supply chain functions at that level.

A review of the schemes of service for various staff involved in HPT supply chain functions in the health sector reveals significant variations from actual practice. The scheme of service for pharmacists covers management of pharmaceutical supply chain and inventory management well. However, it needs expansion to cover HPT as whole. The scheme of service for pharmaceutical technologists covers receipt, storage, and inventory management; assessment of drug requirements based on disease patterns as well as distribution of pharmaceuticals. The scheme of service for nutritionists has no HPT supply chain functions even though nutritionists do handle nutrition products (also covered under HPT). Notably, the schemes of services for medical laboratory technologists; dentists, community oral health officers, dental technologists; radiology staff do not outline any responsibilities for HPT supply chain management yet these professionals handle HPT in their day to day service delivery roles.

13 Ministry of Health. (2015). Kenya Health Workforce Report: The Status of Healthcare Professionals in Kenya, 2015. Nairobi, Kenya: Ministry of Health

2.6.3 Pre-service training

There are more than 40 institutions of higher learning providing courses in business studies and including components on supply chain management. However, these institutions do not necessarily focus on HPT supply chain. On the other hand, the schools offering life sciences courses especially pharmaceutical sciences do not adequately cover the supply chain functions. There are seven universities currently offering Bachelor of Pharmacy programs in Kenya. Pharmacy education is regulated by both the Commission for University Education and Pharmacy and Poisons Board. Additionally, there are 25 colleges that currently undertake training of pharmaceutical technologists at diploma level. Of these training institutions 20 (63%) are public, 3 (9%) faith-based, and 9 (28%) are private. Specialized courses are offered at master's level with a focus on Pharmaceutical Analysis, Industrial Pharmacy, Pharmacovigilance and Pharmaco-epidemiology, Pharmacology, Clinical Practice, and Toxicology. There are disparities in distribution of the institutions with all of them being in 10 (21%) out of the 47 counties in Kenya. Training capacity is estimated at 216 new graduates annually for pharmacists and 815 new graduates annually for pharmaceutical technologists based on indexing of students by PPB.

In terms of HPT supply chain content, these courses have a detailed component on dispensing, but components covering administrative/management aspects of pharmacy including supply chain module are inadequate. There are also gaps in both faculty numbers and skills to deliver these courses. The proliferation of pharmacy education institutions requires a greater and continuous collaboration amongst the regulators and the stakeholders to ensure that pharmacy graduates from these newly established schools are adequately trained and equipped to meet the ever-changing HPT supply chain needs. Courses offered to other cadres such as nurses, doctors who play a significant role in HPT Supply Chain also lack components for supply chain management of HPT. Graduates do acquire experiential learning during their internship programs though the monitoring to ensure that those who supervise have adequate skills and experience is still a challenge for the regulatory authorities.

2.6.4 In-service training

Most of the staff delivering HPT supply chain functions learn on the job with attendance of specific courses on pharmaceutical supply chain management, notably those facilitated with support of development programs. Several in-service courses have been offered in the past, largely with the support of USAID through implementation partners such as MSH, AMPATH, JSI, Chemonics to staff of public sector at central and decentralized levels (service delivery points). These courses have covered quantification and forecasting, targeting pharmacists and pharmaceutical technologists. Continuous professional development is regulated by the licensing bodies/councils and the delivery of the CPD is done in collaboration with professional associations such as the Pharmaceutical Society of Kenya (PSK) and Kenya Pharmaceutical Association (KPA)

Registered pharmacists and enrolled pharmaceutical technologists who intend to practice in their professional capacity are required to apply for practice license upon fulfilling a set of requirements as prescribed under Cap 244 Laws of Kenya. Renewal of the practice license is carried out annually with a fee stipulated by PPB upon fulfilling all requirements.

In addition, registered pharmacists and pharmaceutical technologists are required to practice in licensed premises which include chemists or pharmacies. These facilities are categorized as retail, wholesalers, or manufacturer of pharmaceuticals. Supportive supervision tools for the public health sector cover some aspects of HPT supply chain management and these are considered during supervision. However, the supervision support is sporadic and not adequately funded. There is also inadequate follow up of actions arising supportive supervision process.

2.7 PARTNERSHIPS IN HPT SUPPLY CHAIN

2.7.1 Partnerships

Partnerships in the health sector are guided by Sector-wide Approaches (SWAp). The sector has an elaborate Partnership Framework 2018-2030 that details the sector coordination agenda and structures.

There are five proposed inter-agency coordination committees (ICCs) aimed at strengthening joint planning, coordination, and monitoring of specific investments in the sector. One of them is the Health Products and Supply Chain and Infrastructure ICC that includes representatives from both public and private sectors.

A draft Memorandum of Understanding (MoU) is in place between the Government and Faith-based Health Service Providers aimed at fostering a strong and effective partnership for the achievement of national health goals. The MOU outlines areas of cooperation including HPT under which the Government may consider allocation and distribution of Essential Drugs and Medical Supplies to faith-based health facilities in need of such support. This is envisaged to sustain some of the current support/arrangements in place where GOK distributes essential drugs and medical supplies to Level 2 and 3 (Dispensaries and Health Centres) faith-based health facilities; and also provides commodities for special programmes such as vaccines, TB drugs, ARVs, ACT/AL and HIV test kits to faith-based health facilities as per the existing Government distribution system and regulations. MEDS, the faith-based facilities procurement agency, also services County Governments on a need basis.

2.7.2 Local Production of HPT

Kenya is the hub of pharmaceutical manufacturing within the East African Community with approximately KES 100 Billion worth of annual pharmaceutical expenditure. This is almost 50% of the EAC market estimated at US$ 2.1 Billion in 2017, and approximately 8% of the Sub Saharan Africa's total annual expenditure on medicines. Compounded annual growth rate (CAGR) of pharmaceutical industry is estimated at 9-10%.

Kenya has a total of 32 Local pharmaceutical manufacturing firms[14]. Most of these firms manufacture non-sterile products such as tablets, capsules, syrups, suspensions, ointments, and creams with solid dosage forms and account for approximately 55% of the local

14 Kenya Association of Manufacturers (KAM). 2018. Manufacturing in Kenya Under the Big Four Agenda – A Sector deep-dive report.

products and sterile products account for 2.7%. There are 29 GMP certified manufacturers of pharmaceuticals in Kenya.

Currently there are only two companies that manufacture sterile products. There are only four known companies that manufacture veterinary products, and four known companies that manufacture both human and veterinary products. Majority of the other manufacturers produce human medicines only. The main therapeutic categories are antimalarial, antibacterial, analgesics, anthelminthic, anti-allergies, antifungals, dermatological preparations, and gastrointestinal agents. They also manufacture anti-viral, oral anti-diabetic and antihypertensive products. There are smaller companies that also focus on disinfectants. Kenya's prescription pharmaceutical market was estimated at KES 42.4 Billion in 2018, with expected compounded annual growth rate (CAGR) of 11.8% in 2020. The cardiovascular, diabetes and anti-infective drugs segments accounted for approximately 78% of the total prescription pharmaceutical market. Notably, there are 4 new manufacturers who have put up manufacturing plants that are in the process of starting the production of medicines.

Presently only about 40 to 60% of the capacity of local production is being utilized. 30% of the local market demand is met from local products while 70% is from imported products in terms of value. However, in quantity terms, 50 to 60% of the local market demand is met by locally produced medicines. The largest buyers from the local manufacturing companies is the Government through the Ministry of Health, estimated to account for about 30% of all the prescription drugs in the local market according to UNIDO report of 2010. Kenyan companies undertake mostly secondary and tertiary production of pharmaceuticals. Crude artemisinin is the only Active Pharmaceutical Ingredient (API) currently produced in Kenya and exported 100% for purification. Over 95% of the raw material inputs are imported and cost over KES 25 Billion annually. The bulk of these inputs originate from Asian countries, while some are sourced from Europe. Bulk drugs, (semi-finished medicaments), which form the major raw material inputs for these industries are all imported. Locally sourced raw materials include maize starch, refined sugar, glucose syrup, rectified spirit, ethanol, and sodium chloride and packaging materials. Locally sourced raw materials account for less than 1-2% of the total procurement of raw materials.

Raw materials price account for 50-80% of ex-factory cost of drugs depending on scale of production. Competitiveness of local manufacturers is therefore negatively impacted by dominant importation of API, yet procurement by public agencies is still guided by cost competitiveness in tendering. Similarly, the competition from imported pharmaceutical equivalents is very stiff. The Government has made various efforts towards strengthening the local production of HPT through incentives. Such efforts include exemption of import duty on active pharmaceutical ingredient (API) and indeed all finished pharmaceutical products as well as application of reservation and preferential procurement regulatory provisions in the Public Procurement and Assets Disposal Act, 2015. These incentives are meant to support the local manufacturers to scale up their production while at the same time offering products to Kenyans at affordable prices. The incentives have shown some impact on local production capacity as evidenced by the increasing new investments in the sector. In recent years, two firms have started production and one multinational is under construction.

The preferential procurement of local pharmaceutical products is also an incentive that has enabled purchase of more local products. However, a lot remains to be achieved in the

sector, especially in expanding the market access for the local players who have invested quite heavily in their factories.

According to the Economic Survey Report of 2020, there has been a decline in exports of medicinal and pharmaceutical products over the last five years, with the average annual exports totalling KES 11.2 Billion and accounting for 2.15% of total principal exports. Conversely, imports have been increasing with annual imports for medicinal and pharmaceutical products totalling KES 60.6 Billion and accounting for 3.66% of the total principal imports. The trend of medicinal and pharmaceutical products imports and exports over the period 2015 to 2019 is summarized in the graph that follows.

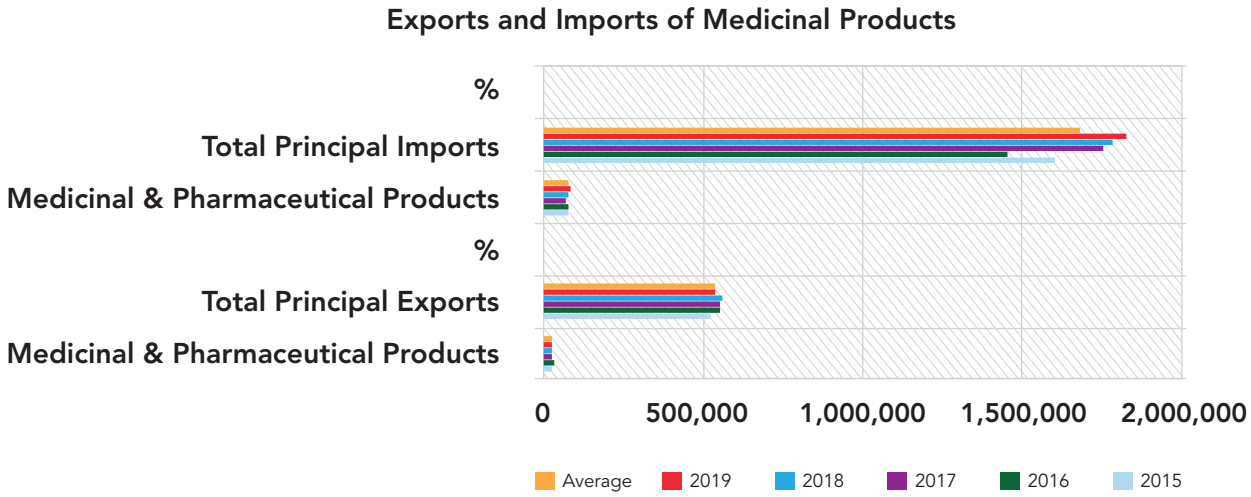

Figure 4 | *Trend of value of HPT imports and exports (2015-2020)*

The significance of HPT in local manufacturing is demonstrated by the inclusion of HPT as one of the priority areas for industrial growth. Manufacture of pharmaceuticals, medicinal chemical and botanical products, was one of the economic activities added during the rebasing of the Producer Price Index (PPI) in 2017. The index is designed to measure the average change in the price of goods and services either as they leave the place of production or as they enter the production process. The weight contribution that was assigned is 1.52%.

The industry remains heavily regulated with the main legislation being the *Pharmacy and Poisons Act, Cap 244*. However, other legislations such as *Food and Drugs and Chemical Substances Act, Cap 254*; *Anti-Counterfeit Act, 2008*; *Industrial Property Act, 2001*, *Factories and Other Places of Work Act, Cap 514*; *Public Health Act, Cap 242*; and *Environmental Management and Coordination Act*, 1999 all have significant impact on pharmaceutical manufacturing firms.

Several studies focusing on the capacity of the local manufacturing industry reveal that the industry's capacity is underutilized – the installed capacity utilization is estimated at 50%-60% on average annually for most dosage forms. Despite the regulation framework and underutilized capacity, competition is still faced from unregulated or "grey imported "medicinal brands that have recently been estimated to have 8% prevalence in the market. These imports pose risks in terms of their questionable efficacy and quality.

The local manufacturing industry faces significant challenges in terms of human resource constraints, heavy reliance on imported raw materials, competition from imported generics, lack of regulatory provisions on pricing, high cost of operations specifically regarding financing, utilities and infrastructure, counterfeits, lack of accurate market data, raw materials procurement hurdles, negative perceptions on local products, prohibitive cost for bioequivalence studies, fragmentation in the distribution and supply chain system, and lack of coherent strategic support for development.

On the other hand, the opportunities are immense, and include the available market and large unmet need; an established policy and regulatory framework; economic and political stability; incentives in terms of VAT exemptions; political commitment to affordable healthcare through UHC; Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities; as well as demand for raw materials as inputs for local manufacture within Kenya and the wider COMESA region.

Recognizing the immense potential for scaling up local production, the government through both the ministries of Industrialization and health developed the Kenya Pharmaceutical Sector Development Strategy (KPSDS) in 2012 and a roadmap for guiding the pharmaceutical industry to attain the WHO GMP Standards through a stepwise approach, the first strategic component of the KPSDS as part of implementation of Kenya National Pharmaceutical Policy (Sessional Paper No 4 of 2012).

The development of the roadmap, with the support of UNIDO, was preceded by a baseline assessment of existing manufacturing practices. Based on the 17 key quality elements of WHO GMP, and categorizations based on physical site characteristics and Quality Management Systems (QMS), seven companies were assessed for compliance on pilot basis. Later in 2012, all 35 licensed manufacturers were assessed based on WHO GMP Standard using Site and Quality Management Risk concept to categorize the level of GMP status. Generally, the level of compliance with the WHO GMP is low with about 8 in category 'A' and 'B' (which is the higher status- at or near GMP) and majority in category 'C'.

The main reason for this low GMP compliance was due to site related quality issues arising from rented premises which made GMP improvements difficult such as, installation of pharmaceutical grade water and HVAC systems. These variations in GMP status necessitated companies to develop program for Corrective Action and Preventive Action (CAPA). Financing quality improvements is costly and affordable financing was identified as a major barrier (and remains a key barrier).

Already the industry players with the support of Ministry of Industrialization are considering various potential projects such as setting up multipurpose chemical plant for bulk production of intermediate inputs, manufacture of non-pharmaceuticals, commercial processing of traditional medicines, processing of locally available sugar, salt (sodium chloride) and ethanol to pharmaceutical grades for use as inputs by pharmaceutical industries, and investment in manufacture of medical equipment.

2.7.3 Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement Flexibilities

The *2001 Doha Declaration* on the TRIPS Agreement and Public Health, reaffirmed the maximum use of the flexibilities and safeguards in the TRIPS Agreement. It clarified matters such as granting of compulsory licenses, determination of exhaustion regimes and facilitation of parallel importation, and use of compulsory licensing in case of insufficient manufacturing capacity. The African Union in its Roadmap for Shared Responsibility and Global Solidarity for AIDS, TB and Malaria Response in Africa echoed the commitment for creation of legislative environment that incorporates the full use of TRIPS flexibilities and develops awareness to avoid the incorporation of TRIPS-plus measures in trade agreements. Further, the EAC developed an Intellectual Property Policy in 2013, with a view to guiding EAC Partner States on recalibrating national IP legislation to enable full utilization of the TRIPS flexibilities.

Towards implementation of TRIPS flexibilities, Kenya revised its Intellectual Property (IP) law, the Industrial Property Act, 2001 and the Trademarks Act, Cap 506 between 2001 and 2017 to facilitate implementation by stakeholders. The criteria for patentability are elaborate and the only inventions that are patentable are those that are new, involve an inventive step and are industrially applicable. Similarly, the process of revoking patents has been simplified, public health aspects that are excludable from patent protection are also clarified, enabling exemption for international exhaustion of patent rights and trade mark rights to allow parallel importation of patented products, enabling use of compulsory licenses and state exploitation of patented inventions (government use), allowing marketing approval before expiry of patent, and controlling anti-competitive practices. Despite the enabling legislation and sustained advocacy, the implementation of the TRIPS flexibilities is worryingly low and has not produced significant impact as anticipated.

The available flexibilities within the TRIPS Agreement are compulsory licensing, parallel importation, voluntary licensing, availability of new use pharmaceutical patents, government use licenses, research exemptions, early working (also known as Bolar Exception) and test data protection. There has been significant use of parallel importation mechanisms, limited use of voluntary mechanisms, but no use of involuntary mechanisms. This is explained by the fact that use of parallel importation, save for development legislation and policy framework, does not require intense action from Government as does licensing, which requires targeted incentives for manufacturers to lower cost of production.

2.7.4 Adoption of GS1 Global Standards

Traceability of HPT within the public health supply chain is currently being done through physical visits to service delivery sites, extensive review and reconciliation of documentation, and comparison of issues data with consumption data. Such audits are time and resource intensive. Further, they also present risks in terms of increased circulation of counterfeits, poor quality, and fake HPT in the Kenya market.

Implementation of the GS1 global standards for verification and traceability of HPT in the supply chain will accord traceability of HPT within the public health supply chain and increase accountability.

The Ministry needs to develop a strategic and coordinated approach for the adoption of GS1 standards for track and trace, in the management of HPT throughout the country. In doing so, the MOH will need to incorporate lessons learnt over the years through industry innovations that will lead to better, more efficient supply chain. Implementation and use of global supply chain standards for product identification, location identification, and product master data, and the adoption of these global standards will reduce costs, improve efficiency, and improve the availability of health commodities in Kenya.

PRIORITY GAPS

- The Partnership and Coordination Framework 2018-2030 yet to be operationalized
- Reliance on imported raw materials
- Dependence on imported medicines
- No legal or regulatory provisions regarding the pricing of medicines
- High cost of operations in terms of financing, utilities, and infrastructure
- Fragmentation in the distribution and supply chain system
- Human resource capacity gaps
- Presence of counterfeits and falsified products
- Lack of accurate market data
- Negative perceptions on local products
- Prohibitive cost for bioequivalence studies

PRIORITY GAPS

- Lack of capacity at NQCL to test all HPT e.g. biologicals, vaccines, newer molecules, medical devices
- Inadequate capacity of NQCL in terms of financing, infrastructure, and human resources
- Inadequate sharing of quality testing analysis reports amongst testing laboratories and stakeholders
- Gaps in PV governance in terms of dissemination of guidelines to facilities and appointment of PV focal persons
- No PV/PMS regulations in Place
- Lack of operationalization of the PV/PMS TWG
- Lack of adequate personnel to effectively perform PMS functions
- PMS strategy is outdated
- Inadequate funding for PMS activities - lack of adequate funding to perform field screening of health products as well as active quality surveys of health products and health technologies
- Lack of integrated data management system for PMS
- Preservice training gaps in prescribing & dispensing practices
- Inadequate/Lack of tools for prescribing and dispensing
- Lack of policy guidelines on prescribing and dispensing
- Lack of enforcement of generic

2.8 QUALITY MANAGEMENT AND RATIONAL USE

2.8.1 Quality Control

The primary institution responsible for quality control as per the Pharmacy and Poisons Act, Cap 244 is the National Quality Control Laboratories (NQCL). NQCL's activities are centrally administered from single location/facility. It is both WHO prequalified and ISO 17025:2005 accredited. Currently, the NQCL is working towards meeting additional requirements for new electronic data integrity requirements from the WHO and new risk management requirements introduced in updated ISO 17025:2017 to maintain certification standards. NQCL has capacity of 3000 samples per year and current turnaround time 42 of working days. It issues analysis report (Certificate of Analysis) to clients and maintain a database on the quality of all medicines that it handles. NQCL lacks capacity to test all HPT such as biologicals, vaccines, newer molecules, and medical devices. It has challenges regarding limited space for expansion, inadequate budget support, maintenance, service, and calibration of equipment. Further, it has experienced limitations in terms of sharing of analysis report with interested parties as well as benefiting from QC testing done by other laboratories.

MEDS also has Pharmaceutical QC Laboratory Services that is WHO pre-qualification and provides QC Laboratory services to firms in Kenya and other African Countries to ensure quality of pharmaceuticals. However, the laboratory is underutilized by the local regulatory authority for purposes of testing products before registration and only utilized for post-market surveillance surveys.

2.8.2 Pharmacovigilance

In terms of pharmacovigilance, the PPB has developed Guidelines on the Safety and Vigilance of Medical Products and Health Technologies (2019) and Guidelines for the establishment of Qualified Persons for Pharmacovigilance QPPV 2018. The board has an elaborate system for pharmacovigilance reporting, a National Spontaneous Reporting system with Individual Case Study Report (ICSR) form. Although, both manual and electronic Systems are available for reporting, between 80-90% of ADR reports are received electronically through the Pharmacovigilance Electronic Reporting System (PvERS). The (PvERS) has a database which is linked to VigiFlow and reports are transmitted to VigiBase, the global ICSR Database.

Several governance structures for PV are also in place such as Quality, Safety and Efficacy Committee that review safety issues, ad hoc advisory committee, and a PV/PMS technical working group. The recent review of Pharmacy and Poisons Act, through the Health laws (Amendments Act) 2019 has also clarified the scope of PV & PMS as functions of the pharmacy and Poisons Board.

Kenya is considered the leading country in terms of pharmacovigilance and PMS in EAC regional Economic block. Towards strengthening PV and PMS, the regulator has steered development of an in-service training curriculum for PV and PMS, as well as PV and PMS Job Aids.

PRIORITY GAPS

- Inactive MTCs at county and facility level
- Low awareness of availability of STGs by clinicians
- Varying prescriber preferences for guidance on treatment protocols
- Low adherence by HCWs to essential HPT lists
- Lack of drug use surveys especially at facility level
- Lack of enforcement of non-compliance as regards unethical promotion
- Inadequate laboratory diagnostic capacity to test for sensitivity to antibiotics
- Inappropriate prescribing and dispensing practices
- Self-medication by patients especially of antibiotics
- Weak enforcement for non-compliance to widespread access to prescription only medicines especially antibiotics
- Lack/inadequate knowledge by clinicians on effective antimicrobial use
- Lack of proper coordination and understanding between PPB and the traditional medicine practitioners
- Lack of clear guidelines for registration of the herbal products
- Lack of capacity for the analysis of traditional and alternative medicines – lack of Reference Standards

2.8.3 Post Market Surveillance

The PPB has a PMS strategy developed in 2011, and PMS Section under Product safety is equipped with three trained full-time personnel. The regulator has Minilabs for supporting PMS and applies field screening technologies such as the Raman spectroscopy. The PMS strategy is outdated, and the board's capacity for PMS in terms of scope of HPT is limited. Although the board has received support from partners such as PHPs (GF), USP/PQM to support PV and PMS activities, it still has limited funding to perform field screening of health products as well as active quality surveys of health products and health technologies.

2.8.4 Rational use

The national medicines and therapeutics committee (NMTC) is operational. However, very few county medicines and therapeutics committees (MTC) and facility MTCs are

operational. The guidelines for MTCs have recently been reviewed but have yet to be widely disseminated. The standard treatment guidelines available are out of date and not comprehensive enough for all priority conditions. In terms of essential lists for HPT, the KEML is now current and the KEMSL and KDL are in the final review stages. It is remarkable that national hospitals, large private hospitals, and MEDS, have formularies despite the non-existence of a national formulary.

Various past surveys have shown high prevalence of inappropriate use of medicines. Such practices include: poly pharmacy; provision of prescription only medicines without prescriptions; stock piling and dispensing of medicines in clinics; poor dispensing and prescribing practices; poor disaggregation of dispensing and prescribing roles, inactive MTCs at county and facility level; failure to apply standard treatment guidelines by prescribers in both public and private sector; self-medication, deficiencies in regulatory capacity especially with regards to enforcement of regulations governing prescription only medicines; traditional Chinese medicines and veterinary products; and, ineffective post-market surveillance and pharmacovigilance systems especially in the private sector. Conducting rational HPT use surveys is not common at national or county level. However, some referral hospitals undertake regular medicine use reviews and utilize the reports for decision-making.

The health sector has pursued several initiatives with a view to strengthening rational use of HPT. At the regulatory level, the PPB has already developed and disseminated PPB guidelines for advertisement and promotion of medicines and medical devices in Kenya (2012) and its application. Facilities also apply guidelines for stock management control. Further, although unstructured, aspects of rational use are incorporated in continuing professional development (CPD) sessions for different professionals in the health sector. Recent initiatives to strengthen antimicrobial safety include development and dissemination of guidelines on antimicrobial safety and embedding the AWaRE classification in KEML 2019 are also significant. Admittedly there is still low awareness levels by patients on their conditions, duration of treatment and possible treatment outcomes.

2.8.5 Traditional and Alternative Medicines

There is a draft policy for the TAM practice and a draft bill for the traditional and health practitioners, aimed at operationalizing the requirements of the Health Act, 2017 - establishment of a policy and regulatory framework for traditional and alternative medicines. Products registration falls under the PPB and there is a listing available for the products especially for alternative medicines but largely comprising imported products. There is a database for the Alternative Medicine Health practitioners is maintained at MOH, Division of TAM while the Ministry of culture maintains the database for traditional herbalists. Currently KEMRI undertakes research for their own TAM products. The Ministry of Health has an operational division that coordinates the TAM agenda with responsibilities for promoting, coordinating, and monitoring implementation of multi-sectoral TAM activities.

Considering that the policy direction has yet to be clarified, there are still significant issues of regulation relating to TAM such as - the current *Industrial Property Act, 2001* does not address the protection of traditional knowledge for the herbal practitioners, including their practice; the National Policy on Traditional Knowledge, Genetic Resources and Traditional

Cultural Expressions is in place, but does not adequately address the herbalists and their products; there is no legal framework and mechanisms for the protection of their product content or treatment; no formal information on the availability of TAM products; inadequate research work for the products in the market has been published; no quality control testing is done for the TAM products; and there is no current pharmacopeia for carrying out analysis of the herbal products or alternative medicine products.

2.9 FINANCING, RESOURCE MOBILIZATION AND PRICING

2.9.1 HPT supply chain financing

The sources of funding for HPT include national government through MOH, county governments, development partners, households, NHIF, private insurers, parastatals, other central government agencies, private employers and non-profit institutions serving households (NPISH). Funding for HPT through NHIF is channelled through public and private hospitals. Out-of-pocket and household expenditures contribute significantly to the total annual national expenditure on medicines.

PRIORITY GAPS

- Over-reliance on external/donor resources for strategic HPT
- Inadequate budgetary allocation for supply chain management costs
- High outstanding debt and pending bills by both MOH and Counties to suppliers including KEMSA
- KEMSA does not have enough resources to ensure commodity availability for all essential health commodities, due in part to funds flow delays and outstanding debts.
- Lack of aggregated pricing data and inadequate sharing of pricing information and other commodity information among key stakeholders
- Lack of a pricing structure for HPT dispensed to clients in levels 4-6 hospitals
- Delays in disbursement of funds for HPT
- Lack of clear Resource Allocation Criteria (RAC) for HPT at the Counties
- Program-Based Budgeting not yet implemented in a way that sufficiently monitors actual spending against programmatic objectives including for HPT.
- High price disparities within and across the dealers' public including hospitals even for similar brands.

The proportion of Public Health Expenditures on Health Products from both government and donors, has stagnated at 15%. Strategic HPT (HIV, TB, malaria, Family Planning, EPI vaccines and Nutrition commodities), except for family planning commodities, are mainly funded by development partners. There is a significant gap in the financing of pharmaceuticals and HPT. The current investments in HPT represent about 22% of the required investments, with 20.7% for essential medicines. Donors invest about KES 77 billion per year in the 3 major communicable diseases meeting 92% of those HPT need with government meeting the less than 10% difference in program HPT needs. In the 2015/16 FY, allocation towards HPT accounted for only 2.9 % of Current Health Expenditures. County government allocations to HPT, have decreased from 14.6 percent in FY 2016/17 to 10.1 percent in FY 2018/19[15]. However, the absolute amounts spent by counties on HPT from KEMSA increased from KES 2.2 Billion in FY 2013/14 to KES 5.9 Billion in FY 2018/19[16]. These amounts are still low considering that only 46% of the estimated quantified HPT requirements are met. Further, allocations are largely for the products themselves leaving a huge gap in other supply

15 Ministry of Health. 2019. National and County Health Budget Analysis FY 2018/19

16 KEMSA Financial Statements

chain functions costs such as distribution, warehousing, inventory management, quality management, HRH and monitoring and evaluation.

Kenya Medical Supplies Authority (KEMSA) operates a revolving fund business model for the supply of Essential HPT, having been initially capitalised in 2013, to the tune of KES 8 billion though it has not received additional seed capital for to support HPT PSM functions. KEMSA re-configured its business model to align itself with the devolved system of government to ensure that public health facilities access medical commodities. Under the new not-for-profit self-sustaining commercial business model, the county health facilities order and pay for their medical commodities on a demand driven supply system. The funds acquired from these sales goes towards replenishing stock. Sustainability of this model is hampered by delays in payments by counties and other facilities such as national referral facilities. At the national level, KEMSA receives grants from MOH to support its overhead costs. However, the amounts are unpredictable and have been fluctuating over the years.

Budget execution for procurement continues to be hindered by a series of bureaucratic delays related to approval of the procurements, specifications for the commodities, nominations to tender committees and delayed delivery. It is worth noting that county governments have huge budgetary constraints with significant proportions of their annual allocations going to recurrent expenditure, particularly personnel emoluments and very little fiscal space is left for such items as HPT. The flow of funds to facilitate the procurement and supply chain management of HPT at both national and county level is also unpredictable. HPT supply chain also grapples with issues of equitable resource allocation and debt management. Currently, there are inadequacies in equity in resource allocation for HPT across counties and within counties to health facilities.

Previously, resource allocation criteria (RAC) used for allocation of HPT to rural health facilities (dispensaries and health centres) was based on infrastructure, under-five's morbidity, poverty levels, HIV/AIDS cases, female population of reproductive age (15-49) and geographical area, while the one for then district hospitals, the RAC variables were poverty, beds utilization, Out-Patient- Cases, Accident Prone Facilities and Fuel Costs. There is no current evidence of counties using an appropriate RAC to ensure equitable access to HPT within the county facilities.

Debt issue cuts across public and private sector. In the FY 2018/19, KEMSA's receivables from counties and MOH stood at KES 5.2 Billion. Considering that the public health sector also procures from the faith-based and private sectors, the amounts owed by public agencies to suppliers are deemed high. Delayed payments by clients is a big concern for manufacturers, distributors, and wholesalers in Kenya. However, lack of credit information sharing among players makes it difficult to quantify the magnitude of the outstanding debt problem. The delayed payments end up translating into high prices of commodities as suppliers attempt to recoup their financing costs.

In accordance with the Public Finance Management Act 2012, the National Treasury is responsible for mobilizing domestic and external resources for financing national and county government budgetary requirements and putting in place systems to ensure transparent financial management and standard financial reporting. To accomplish this, the National Treasury uses the Integrated Financial Management Information System that captures all

costs and expenditures and accounts for all funds transparently. Bilateral donors channel resources through agencies based on memoranda of understanding. Funding made available through the government systems is subject to both internal audit and external audit by the office of the Auditor General. Resources disbursed and managed by funding agencies are audited in accordance with their respective rules and regulations. The flow of expenditures through a health system is tracked using the National Health Accounts methodology, which links the sources of funds to agents and subsequently service providers and monitors the uses of funds by functions and services.

2.9.2 Pricing of HPT in the HPT supply chain

Prices of HPT in Kenya are unregulated and generally higher than those in other EAC countries. Recent reviews, such as HAI Pricing study and KEMSA Assessments, indicate that KEMSA and MEDS have been able to negotiate for competitive prices compared to international reference prices, leveraging on economies of scale. Similarly, market price surveys undertaken have also aided in negotiations of prices during tendering. Sourcing from local producers has increased. However, the prices for HPT charged to patients at the public health facilities and faith-based facilities have not always reflected these gains owing to add-on charges.

In the private for-profit sector, the variations in pricing of HPT are high. Retail prices in the low-income settlements have been noted to be higher than corresponding international reference prices and vary across regions despite similarity in socio–economic status. Prices in the private sector have been noted to be higher than the international reference prices, and for some products more than 30 times.

Various assessments and studies in the health sector have attributed the unaffordable prices for HPT to the factors including high cost of local production, inadequate consumer information, inadequate availability, lack of agreed framework of operation between private and public health facilities, lack of data on HPT price trends and components, unjustifiable mark-ups along the distribution chain, fragmentation of sources, lack of coherent policy guidance on pricing of HPT, gaps in regulation with regards to registration of products, and corruption.

Kenya as a liberalized market has been strengthening the business environment, promoting healthy competition in the economy while improving regulatory efficiency. These initiatives take into consideration the global and regional context while at the same time embedding consumer protection. Where there has been market failure in achieving availability of essential commodities at fair prices, the government has intervened for instance through the *Price Control (Essential Commodities) Act of 2011*, the *Energy Act, 2011* in the case of petroleum products. The prices paid by patients for HPT are also influenced by the prescribing practices. Prescribing, dispensing and procurement of medicines by brand or trade names is still a common practice in Kenya. Presence of falsified (counterfeit) and substandard HPT in the market also poses a challenge in terms of safety to patients as well as fair competition.

PRIORITY GAPS

- Inadequate coordination structure for M&E of HPT supply chain
- Lack of clearly defined performance indicators and targets
- Inadequate support for HPT supervision
- Poor data quality in both public and private facilities
- Fragmentation in monitoring system
- Inaccurate reports
- Inadequate HPT data analysis and visualization both at the county and national level
- Variability in reporting rates for various HPT categories attributable to availability of tools and partner support
- Inadequate review of facility reports compromising quality of HPT data
- Sporadic Data Quality Audits for HPT.

2.10 MONITORING, EVALUATION AND RESEARCH

2.10.1 Monitoring and Evaluation

The health sector monitoring and evaluation framework is detailed in the Monitoring and Evaluation Plan that lays out the broad principles and plans for managing monitoring and evaluation in support of implementation of the Kenya Health Sector Strategic Plan (KHSSP) for the period 2018-2023 as well as the Universal Health Care (UHC) and Primary Health Care (PHC) core agenda. The M&E Plan also clearly outlines responsibilities for M&E functions at the various levels of the national health system. Additionally, it details the measurement system in terms of indicators and targets for the KHSSP both from a sector strategic objectives perspective, and health orientations or investment areas.

It also provides the sector indicators and targets for UHC and PHC implementation as well as specific monitoring mechanisms and evaluations to be performed. This review appreciates that monitoring and evaluation of HPT Supply Chain objectives is critical in ensuring that the health sector achieves it overall policy objectives.

The Division of HPT at MOH has recently initiated the development of a M&E framework focusing on HPT to support implementation of UHC. This framework attempts to cover the various HPT supply chain and technical aspects from product selection and forecasting, procurement, quality assurance, distribution, storage, and rational use. It complements existing initiatives led by the MOH M&E unit and is expected to enhance visibility of HPT Supply Chain M&E data, technology leverage, and follow-up on M&E action plans.

The MOH developed Guidelines for Institutionalization of M&E in the health sector in 2016. Other tools developed to support strengthening of data for decision-making include: County M&E frameworks, Standard Operating Procedures for varying aspects of data management, Data Quality assurance protocol, joint supervision checklists, and reporting templates and guidelines. However, these guidelines are not widely disseminated across the levels of the health care system.

It is apparent that there are inadequacies in the current HPT supply chain in terms of measurement and mechanisms to embed performance and accountability. An elaborate and sustainable HPT supply chain M&E system, linked to the overall national M&E Framework for effectiveness should be established to fill in the persistent gaps in M&E.

There is evidence of utilization of HPT LMIS reports in the generation of orders for facilities especially with regards to priority programs. However, various reviews have revealed

inadequate data utilization in processing of orders. Monitoring mechanisms undertaken include county forums for county managers responsible for HPT (mainly county pharmacists and county laboratory coordinators. Such forums review progress of implementation of activities and address identified bottlenecks. Key performance indicators included in the M&E Plan and reviewed performance frameworks for priority programs – lacked baselines.

Its commendable that national agencies involved in key HPT supply chain functions such as KEMSA, NQCL do produce annual reports as part of the AWP monitoring, and in line with their respective mandates, and that joint assessments with county government teams routinely include HPT issues. Reporting tools on DHIS are available and standardized and are acknowledged as a significant contributor for effective monitoring of stock status, pipeline and overall commodity security.

Other gaps identified in M&E include: lack of coordinated framework for HPT M&E with the function fragmented by vertical programs and divisions at MOH, especially for programs that are heavily donor funded; a national framework for supervision is not well institutionalized; most policies and strategies outline some M&E issues but not comprehensively; national DQAs do not routinely include HPT indicators save for a few programs such as TB.

PRIORITY GAPS

- No clear linkage of domestic research and burden of diseases or mortality rate as an input into prioritization of essential HPT
- Inadequate capacity to undertake policy relevant and demand driven research
- Loose linkages between academia, research, and practice for HPT (most research is on health systems)
- Inadequate funding for research on HPT
- Lack of a clear HTA implementation pathway for the health products and technologies.
- Inadequate technical capacity to undertake HTA exercise

2.10.2 Research and Development

Research on HPT and HPT supply chain has been undertaken at various levels in both public and private sector. Most of the research at county level is undertaken at the county referral health facilities in collaboration with institutions of higher learning and implementation partners supported by donors. Several studies have been undertaken around HPT at service delivery points in counties focusing on access, availability, and costing. However, dissemination and attendant linkage to decision-making in planning and policy is inadequate.

The main agency in carrying out HPT research has been KEMRI. The agency has supported MOH on the rational use of anti-malarial drugs, and changes in national malaria treatment policy due to anti-malarial resistance; development of treatment regimens that have substantially reduced the treatment period for leprosy, tuberculosis and leishmaniasis (kalazar); development and commercialization of diagnostic kits for HIV 1 and 2 and viral hepatitis; strategic advisor on rationalization and regulation of traditional medicines and stewarding the identification of potentially useful traditional medicines for asthma, epilepsy, diabetes, hypertension and malaria that are in various stages of commercialization. Dissemination of research findings is carried out through conferences and particularly the Annual Scientific and Health conference (KASH). KEMRI has also been instrumental in conducting vaccine trials such as Ebola clinical vaccine trials, pneumococcal vaccine

trials; and in supporting county governments to conduct food handling certifications for the hospitality industries [17].

Notably, KEMRI relies heavily on external funding and as at 2017, had mobilized research grants cumulatively worth over KES 20.1 Billion. Over 70% of research funding has been from external sources and manifesting a declining trend over the last decade. Funding from the government and internally generated sources stagnated at about KES 2.3 Billion. Funding for research also accounts for a very small proportion of the health budget (~3.5%). KEMRI has developed and marketed diagnostic kits such as for culture Media (plates), culture media (Tubes), KEM-rub, TBcide, KEMTAQ, Safi Kem (Hand wash), Sheep blood and distilled water, Rift Valley Fever testing kit.

There is no clear focal point (and engagement frameworks) that coordinates HPT supply chain research within MOH. Further, there is no clear linkage of domestic research and burden of diseases or mortality rate as an input into prioritization of essential medicines and treatment regimens. The linkages to pharmaceutical sector are also weak and thus may not effectively drive innovation and production of HPT. Research agenda is further stifled by inadequacies in capacity to undertake policy relevant and demand-driven research, and poor coordination between the ministries of higher education and Health with regards to the development of research areas.

2.10.3 Health Technology Assessment

Health Technology Assessment (HTA) is a platform for scientifically establishing the evidence regarding clinical effectiveness, safety, and cost-effectiveness of any given technology in response to community needs. The case for HTA has been well articulated and initial steps laid out through inclusion in legislation (Health Act, 2017), policy documents, and select MOH staff training. Several efforts have been made to carry out HTA functions such as KEML development, MES project implementation, capacity building through trainings of MOH staff by Thailand Government on HTA, and ensuring that HTA is embedded in policy documents such as Kenya Medical Devices, KHP and KHSSP. For further progress to be made, and fully benefit the HPT supply chain, in this area there is need for a clear roadmap for HTA, including coordination structures and capacity building.

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2.11 CONCLUSION

This review and analysis have brought out several critical challenges that stifle full and effective functionality of the health products and technologies supply chain in both the public and private sector. Challenges relate to the core functions of the HPT supply chain including regulatory, policies and procedures; quantification, procurement, warehousing and inventory management, distribution, service delivery and utilization; as well as cross-cutting issues such as financing, information management, human resource, governance and coordination. In prioritizing the gaps, this strategy appreciates these broad themes are interrelated and interdependent.

- Inadequacies in capacity for governance, regulation, and quality assurance
- Opportunities to optimize product selection, quantification, procurement, and distribution building on promising practices in both public and private sectors
- Gaps in human resource management and performance management stifling delivery of HPT functions across both public and private sector
- Optimization of HPT information management systems to improve data availability, accessibility, and utilization across the entire HPT supply chain
- Opportunities for scaling up research and development and scale up of local production capacity for HPT as well as exploitation of TRIPS Agreement flexibilities.
- Need for improved coordination of stakeholders and partners for effective resource mobilization, allocation, and monitoring and evaluation.

CHAPTER 2

CHAPTER 3:
STRATEGIC DIRECTION

CHAPTER 3

3.1 STRATEGY FRAMEWORK

Universal access to quality essential medicines, essential health technologies and pharmaceutical services in Kenya is the desired overall goal for the Health Products and Technologies Supply Chain as per the HPT Policy. As such, ensuring that HPT of appropriate quality, efficacy and safety are available, accessible, affordable, and rationally used is the overall goal of this strategic plan. This strategy is guided primarily by the principles of equity, public participation, multi-sectoral collaboration, efficiency in application of health technologies and mutual consultation and cooperation between the public and private sectors of healthcare, national and county governments engendered in the Kenya health policy.

This strategic plan envisions a health sector with "A sustainable, resilient and responsive health products and technologies supply chain system". A set of strategic priority areas have been identified to support the achievement of this vision. Further, strategic interventions in these priority areas have been elaborated. To guide and enable implementation by stakeholders, the strategic interventions are translated into a detailed implementation plan with responsibilities, timelines, and costs estimates (Annex I).

HEALTH PRODUCTS AND TECHNOLOGIES SUPPLY CHAIN STRATEGY 2020-2025

VISION: A sustainable and resilient and responsive health products and technologies supply chain system

MISSION: To provide a steady supply of quality and affordable health products and technologies through a functional supply chain system

APPROACHES

- Reduce inequities in HPT supply chain
- Promote good governance through information sharing and community participation
- Promote integration and multi sectoral collaboration while optimizing the role of the Ministry of Health in coordination
- Strengthen HPT supply chain capacity and resilience
- Leverage on technology in all HPT supply chain functions

GUIDING PARAMETERS

- AVAILABILITY
- QUALITY
- AFFORDABILITY

STRATEGIC PILLARS

STRATEGIC PILLAR 1	Enhance Capacity for Governance, Regulation and Quality Assurance
STRATEGIC PILLAR 2	Establish and Sustain a robust HPT Product Selection, Quantification and Procurement, Distribution and Use System
STRATEGIC PILLAR 3	Harness collaboration and partnerships at all levels for effective resource mobilization and implementation
STRATEGIC PILLAR 4	Embrace and Adopt Information Communication Technology in all aspects of supply chain for HPT
STRATEGIC PILLAR 5	Scale up Capacity for Research, Local Production, and full exploitation of TRIPS flexibilities for Health Products and Technologies
STRATEGIC PILLAR 6	Strengthen Human Resource Management and Development for HPT supply chain

M&E: Measurement, Learning and Accountability

3.2 STRATEGIC PILLARS

This section details the strategic pillars, strategic objectives, expected outcomes and key performance indicator for the strategic plan period 2020-2025.

STRATEGIC PILLAR 1

Enhance Capacity for Governance, Regulation and Quality Assurance

The legislative and regulatory framework will be strengthened to ensure compliance and assure quality throughout the supply chain for health products and technologies. Policy, legislations, and guidelines in the pipeline will be processed and disseminated widely. Critical HPT governance structures (committees and technical working groups) will be activated. The capacity of regulatory institutions will be enhanced and coordination amongst stakeholders facilitated.

Outcome: An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious HPT by the population.

Key Performance Indicators

1. Proportion of functional Medicines Therapeutic Committees at hospital level.
2. Proportion of health products and technologies sampled from post-market surveillance that fail quality tests.
3. Number of locally produced TAM products registered.
4. Existence of an integrated regulatory authority.

Strategic Objective 1.1:

Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices

1.1.1 Enact legislation for a single regulatory body for regulation of HPT in line with Health Act, 2017.

1.1.2 Review PPDA Act, 2015 - Regulations for 2020 to accommodate multiple awards for HPT.

1.1.3 Review Health Laws (Amendment) Act, 2019 to provide for alternatives sourcing of HPT in the event of inadequacies from KEMSA.

1.1.4 Develop regulations to facilitate enforcement of prescribing and dispensing by generic/INN names.

1.1.5 Develop guidelines for professional and ethical conduct by manufacturers, wholesalers, and retailers.

Strategic Objective 1.2:
Review national pharmaceutical policy of 2012 /develop new HPT policy

1.2.1 Undertake midterm review of the National Pharmaceutical Policy (NPP) 2012 to inform the review process/development of the new HPT policy.

1.2.2 Review NPP 2012/Develop new HPT policy.

1.2.3 Develop and disseminate HPT pricing guidelines.

1.2.4 Develop and disseminate guidelines for promoting local production of HPT.

1.2.5 Develop and disseminate guidelines for promoting full exploitation of TRIPS Flexibilities

1.2.6 Develop and disseminate policy guidelines for linking of HPT quantification, procurement and the MTEF planning and budgeting cycle.

1.2.7 Develop and disseminate guidelines on HPT supply chain information availability (transparency) detailing minimum standards for information availability to stakeholders to enhance public participation.

A conducive policy, legal and governance environment is critical for achievement of HPT Supply Chain Objectives, and ultimately assurance of uninterrupted availability of affordable quality HPT to all Kenyans. Policy direction on HPT provided by the national government is the anchor for implementation of strategies at all levels of the healthcare system. Indeed, successful application of standard treatment guidelines, formularies and essential lists for medicines, medical supplies and devices is contingent upon policy and regulatory environment. Further, there is an imperative for establishment of a robust structured function at the Ministry of Health with the full responsibilities for systematically overseeing all functions regarding HPT supply chain management needs for national and county governments in a more integrated and coordinated fashion including management information systems and human resource development.

Strategic Objective 1.3:
Enhance oversight functions for bodies charged with financing, procurement & supply, and regulation of HPT to optimize efficiency

1.3.1 Establish a robust oversight mechanism for KEMSA

1.3.2 Establish a robust oversight mechanism for PPB/KFDA

1.3.3 Establish a robust oversight mechanism for NHIF

1.3.4 Establish mechanism for collaboration and joint working for regulatory bodies tackling HPT related issues (Professionals Regulatory bodies, KEBS, KVB, KHPOA)

1.3.5 Establish a system for monitoring and reporting on compliance with existing regulations

1.3.6 Carry out periodic review and gap analysis of existing regulations and enforcement capacity and performance

Strategic Objective 1.4:
Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship

1.4.1 Elevate the division of HPT to directorate level with clear mandate, organization structure, functions, and establishment.
1.4.2 Progressively operationalize the directorate to the desired staffing level and capacity.
1.4.3 Provide support to county departments of health (CDOH) to establish HPT governance structures.
1.4.4 Develop a capacity building program for the staff of the MOH HPT function guided by the staffing needs assessment.

Strategic Objective 1.5:
Re-establish NQCL as a department/directorate of PPB KFDA with professional semi-autonomy and strengthen quality assurance systems

1.5.1 Provide for the above type of establishment in the KFDA legislation.
1.5.2 Develop a protocol and platform for information sharing with key stakeholders and other HPT quality assurance laboratories.
1.5.3 Enhance capacity (numbers, skills, and technology) of NQCL to undertake full complement of HPT quality assurance tests.
1.5.4 Establish regional analytical laboratories for HPT.
1.5.5 Support NQCL to continuously upgrade and maintain WHO and ISO 17025 prequalification certification scheme.
1.5.6 Expand the research capability of NQCL to offer full range of HPT tests.
1.5.7 Strengthen collaboration linkages with select institutions and programs.
1.5.8 Enhance use of technology in quality management including a database for tests.

Strategic Objective 1.6:
Strengthen Pharmacovigilance and Post Market Surveillance Program

The HPT supply chain quality assurance will be strengthened in a holistic manner including quality standards, regulations, and indicators to assist in quality assessment, inspection, testing, and monitoring. Implementation of the strategic interventions proposed will lead to improved quality testing ranges and capacity, improved testing turnaround times, and compliance with international requirements, and ultimately quality HPT. Strengthened pharmacovigilance will improve the ability to identify, document, prevent adverse events and report the same when they occur. Development and implementation of regulatory framework for traditional and alternative medicines will enhance confidence in TAM products and improve availability and variety of HPT, hence improved quality, and health outcomes

- **1.6.1** Gazette pharmacovigilance (PV) regulations/rules.
- **1.6.2** Undertake regular and sustained dissemination (including sensitization) of the pharmacovigilance guidelines to public and private entities dealing with HPT.
- **1.6.3** Update the PV reporting system (PvERS) to include all HPT.
- **1.6.4** Prepare and disseminate quarterly PV reports
- **1.6.5** Appoint members of the PV/PMS Advisory Committee.
- **1.6.6** Develop and gazette PMS regulations.
- **1.6.7** Review/Update the PMS strategy.
- **1.6.8** Develop guidelines, SOPs and job aids for PMS.
- **1.6.9** Develop a sustainable capacity building program for PV and PMS for the all the key stakeholders (PPB, KEMSA, NQCL, MEDS, MOH, CDOH, private and faith-based health facilities).
- **1.6.10** Establish budget lines for PV and PMS at all levels.
- **1.6.11** Develop an integrated data management system for PMS that enables tracking all the quality aspects of health products in Kenya.

Strategic Objective 1.7:
Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects

- **1.7.1** Finalize and disseminate the new TAM Policy
- **1.7.2** Finalize the development of TAM Bill and enactment of TAM legislation and regulations
- **1.7.3** Operationalize various components of TAM regulations e.g. registration, PV, PMS of TAM products
- **1.7.4** Develop a database for TAM products, practitioners, and practices
- **1.7.5** Develop and roll out TAM research guidelines
- **1.7.6** Develop and implement an incentive scheme for promoting research in TAM
- **1.7.7** Sensitize Traditional and Alternative Medicine practitioners on quality control testing
- **1.7.8** Establish mechanism for information and platform for knowledge exchange on TAM with other countries
- **1.7.9** Develop a national TAM pharmacopeia to support quality and safety testing of TAM products

Strategic Objective 1.8:
Institutionalize Health Technology Assessment (HTA) in HPT management

- **1.8.1** Develop an overarching Health Technical Assessment policy for Kenya to cover all HPT.
- **1.8.2** Develop a national HTA roadmap.
- **1.8.3** Build capacity for HTA at national government HPT supply chain agencies and county governments.
- **1.8.4** Increase stakeholder involvement at public and private sector, and both levels of government throughout the HTA process to help capture and improve the create value and applicability of HTA.
- **1.8.5** Undertake surveys to assess utilization of HTA in HPT Supply Chain planning and decision-making such as pricing and, market authorization for HPT.

The country's health sector is cognizant of the need for coherent, comprehensive, and coordinated product selection, quantification, procurement, and distribution of HPT in

STRATEGIC PILLAR 2

Establish and Sustain a robust HPT Product Selection, Quantification, Procurement, Distribution System and Use

improving availability and accessibility of HPT and overall health outcomes. The urgency for such a mechanism is even greater with the recent requirements for all public health facilities to source HPT exclusively from KEMSA, and the countrywide affordable Universal Health Coverage (UHC) scale up agenda. The public health sector plans to replicate the notable coordination experiences of the national and county treasuries in medium term planning and budgeting in strengthening the quantification process in terms of scheduling, communication through circulars, community participation, consolidation, and tracking. Capacity for procurement, storage, and distribution will be enhanced in a rationalized manner for cost effectiveness. Additionally, a comprehensive program for promoting rational use of HPT will be developed and rolled out across all levels of the HPT Supply Chain

Outcome: An effective and efficient system that ensures quality HPT that are responsive to priority needs, available and accessible to the population.

Key Performance Indicators

1. Proportion of Health facilities with stock out for the tracer essential HPT for 7 consecutive days in a month.
2. Availability of tracer basic equipment (%).
3. Order fill rate for tracer HPT (%).
4. Average lead time from ordering to delivery at health facility.
5. Proportion of health facilities meeting minimum standards for HPT storage.
6. % of health facilities with HPT waste backlog.
7. Proportion of prescriptions for different conditions complying with approved standard treatment guidelines and protocols; and essential lists for HPT.

Strategic Objective 2.1:
Ensure that all health products and technologies for the health system are responsive to the priority needs in line with concept of essential HPT

2.1.1 Establish a system for regularly reviewing priority health needs and revising the essential HPT lists.
2.1.2 Complete development and validation of essential medical devices list.
2.1.3 Disseminate the essential HPT lists for medicines, medical supplies, and medical devices (non-pharmaceutical supplies and medical equipment).
2.1.4 Plan for review, update and dissemination of essential HPT lists every two years (next one due in 2022) to ensure relevance and usefulness.
2.1.5 Review, update and disseminate standard clinical and referral guidelines.
2.1.6 Develop a national formulary for essential HPT.
2.1.7 Undertake surveys on adherence to essential lists for HPT in procurement, prescribing, and dispensing across all levels.
2.1.8 Carry out studies on adherence to the standard treatment guidelines.
2.1.9 Avail the finalized essential HPT lists and STGs on MOH and County websites for increased accessibility.

Strategic Objective 2.2:
Establish and sustain a system for timely and accurate quantification of health products and technologies at all levels of the health system

2.2.1 Enhance coordination and capacity for demand planning of HPT at national and county, and facilities for effective and reliable of HPT.

- Clarify roles and responsibilities for quantification of laboratory supplies and medical devices.
- Disseminate guidelines for HPT demand planning to national programs, county governments and health facilities.
- Develop a national harmonized capacity building program for demand and supply planning incorporating all priority program aspects and essential lists.
- Share quantification tools and outputs amongst stakeholders (through the coordination committees at national, county and facility levels) leveraging on HPT/Commodity Management Information System (CMIS).
- Revitalize the role of HPT Technical Working Groups in quantification.
- Review preservice and in-service courses related to HPT supply chain to ensure they contribute to demand and supply planning.
- Automate forecasting and quantification functions at all levels ultimately integrating with the DHIS2 system.
- Undertake training of HPT supply chain staff on the use of automated forecasting and quantification tools.
- Link last mile demand to Upstream (KEMSA) supply planning.

2.2.2 Develop and/or review where necessary, quantifications for all essential HPT for the strategic plan period.

- Undertake quantification exercise for all essential HPT using a time

series of 3 years, based on consumption and/or services data supported by automated information systems at all levels applying a bottom up approach.
- Review the HPT forecasts annually and make necessary adjustments.

2.2.3 Closely track quantification process at all levels.
- Develop and disseminate a comprehensive calendar for HPT quantification process that is aligned to the national MTEF budget and planning cycle.
- Ensure all counties complete HPT quantification in time through close follow up.
- Enhance accuracy of HPT demand forecasting through structured review process.
- Undertake monthly review of stock reports against quantifications undertaken to track performance targets by HPT categories and make corrective actions.
- Track adherence of procurement to county HPT supply plans and adjust as appropriate.

Strategic Objective 2.3:
Ensure essential Health Products and Technologies are sourced in a cost effective and efficient manner

There is need to ensure that HPT are procured consistently and meet laid down standards for quality, and that the quality standards are upheld at all stages of the procurement process. Further, there is also need to minimize fragmentation in public sector procurement of HPT and ensure that the best possible prices are achieved by applying pooling mechanism or taking advantage of economies of scale. Knowledge and promising practices sharing between private and public sector is also important. This strategy anticipates that procurements will be undertaken efficiently while adhering to applicable procurement laws, mandates, best practices, and regulations.

2.3.1 Update and harmonize policies, legislation, guidelines, and manuals to support effective procurement of HPT.

- Align the *KEMSA Act,2013*; *Supplies Practitioners Management Act, 2007*; *Health Laws (Amendments) Act, 2019* and *Pharmacy and Poisons Act, Cap 244* to support HPT supply chain procurement.
- Revise Health Laws (Amendment) Act, 2019 to facilitate acquisition of HPT by county government and public health facilities regarding products that KEMSA may be unable to supply.
- Update the Public Health Sector Procurement Manual (2009).
- Update KEMSA list in line with essential lists for HPT.
- Harmonize the KEMSA Procurement Policy with PPAD Act, 2015 Regulations of 2020.
- Disseminate the emergency HPT Supply Chain framework.
- Operationalize multiple awards regulation.

2.3.2 Strengthen coordination of HPT procurement and procurement planning functions to minimize fragmentation/duplication.

- Enhance collaboration between the HPT Coordination units at County governments and the County Supply Chain Functions.
- Strengthen coordination of HPT procurement and procurement planning functions to minimize fragmentation/duplication.
- Establish County HPT Coordination Units with clear structures, mandate, and staffing.
- Undertake joint planning for HPT procurement between partners and government with transparent scheduling.
- Revitalize the procurement coordination role for the Division of HPT at MOH; and replicate the arrangements at county governments.
- Develop an integrated multi-year procurement financing plan with clear stakeholder commitments.

2.3.3 Undertake capacity strengthening in procurement of HPT.

- Establish a technology-based system for monitoring utilization of essential lists across public and private sectors.

- Develop a program for strengthening capacity of the sector in HPT contracts management, in collaboration with the private sector.
- Establish a national platform for integrated procurement and information management systems.
- Strengthen the capacity and position of the MOH, HPT Division for effective oversight of HPT across the sector.
- Strengthen the procurement capacity for HPT sector, especially with regards to vendor performance management, use of technology, openness, and fair competition.

2.3.4 Improve transparency in procurement of HPT

- Publish lists of prequalified suppliers in the public sector at national, county and facility levels.
- Promote information exchange and sharing on HPT procurement in private and public sector.
- Advocate for the use of essential lists and formularies for HPT in the private sector.
- Improve information sharing regarding tendering processes including justification for splitting tenders, use of preserved and preferential mechanisms.

2.3.5 Procure health products and technologies including pharmaceuticals, general medical supplies, dental supplies, specialized medical supplies for assistive technologies (orthopedics, occupational therapy, physiotherapy) personal protective equipment, blood transfusion supplies, laboratory reagents, and medical imaging supplies.

2.3.6 Enhance reforms in procurement including supplier capacity development to improve affordability of HPT.

- Promote and advocate for pooled procurement of HPT in the private sector.
- Establish robust price reference framework mechanism for HPT for both public and private sectors.
- Strengthen supplier performance monitoring capacity.
- Establish an electronic based system of measuring and managing supplier performance.
- Harmonize and simplify systems and status for exemption from custom duties and taxes for HPT.
- Improve monitoring of custom clearance process for efficiency and effectiveness (timeliness and allocation of funds).

2.3.7 Increase utilization of technology in HPT procurement planning and procurement.

- Enhancement of technology capacity to support HPT procurement planning and procurement.

- Development of a structured program for ICT capacity enhancement covering all HPT Supply Chain functions across all levels.

- Identify and implement information systems to ensure that procurement processes and results are visible to appropriate stakeholders.

Strategic Objective 2.4:
Improve storage capacity at national and county levels

2.4.1 Undertake rationalized infrastructure improvement for storage and handling especially at level 3 and 2 facilities.
2.4.2 Develop and disseminate storage and inventory SOPs.
2.4.3 Enforce Good HPT inventory management practices.
2.4.4 Institute a capacity strengthening program for staff on HPT inventory management.
2.4.5 Enhance the involvement of private sector in provision of leased storage spaces (National/central stores in the Counties).
2.4.6 Expand KEMSA's storage capacity in Nairobi and the regional depots.

Strategic Objective 2.5:
Embrace ICT in warehousing and distribution

2.5.1 Scale up warehouse management system (WMS) in stores management/ records.
2.5.2 Digitize records where possible in a phased approach e.g. starting with all level 5 and 4, then 3 and 2.
2.5.3 Set up systems for end-to-end visibility of HPT in the supply chain.
2.5.4 Implement transport management systems to improve visibility of goods on transit.
2.5.5 Automate proof of delivery documentation.

Strategic Objective 2.6:
Strengthen the distribution network to the last mile based on sector needs

2.6.1 Advocate for increased resources/funding for distribution of HPT.
2.6.2 Expand KEMSA distribution network (beginning with Kisumu and Mombasa regional depots).
2.6.3 Establish mechanisms for intra- and inter-county re-distribution to reduce wastage.
2.6.4 Set up robust system for reverse logistics.

Strategic Objective 2.7:
Improve order processing and receipt management

2.7.1 Streamline pick, pack, and ship processes at KEMSA with additional order assembly lines.
2.7.2 Maximize on integration of orders both for programs and EMMS.
2.7.3 Develop guidelines on reverse logistics management for HPT.
2.7.4 Develop order scheduling plan with, and for Counties.
2.7.5 Develop, communicate, and execute a county ordering schedule to reduce order turnaround time.

2.7.6 Sensitize health facility staff and third- party logistics firms (3PL) on good receipt practices.

Strategic Objective 2.8:
Develop and implement a comprehensive rational HPT use program

2.8.1 Establish and operationalize medicines and therapeutic committees (MTC) at national, county and hospital level.
2.8.2 Establish NMTC as a statutory committee and covering all HPT.
2.8.3 Support county and hospital MTCs to carry out operational research on management and use of HPT.
2.8.4 Strengthen inventory management for HPT at all levels.
2.8.5 Develop and implement a program for strengthening rational use of HPT amongst health workers.
2.8.6 Develop a National HPT formulary
2.8.7 Advocate for a review of preservice training curriculum for health workers to incorporate elements of HPT management (selection, quantification, procurement, inventory management, prescribing and dispensing.
2.8.8 Review and develop an integrated in-service curriculum for capacity building of health workers on HPT management.
2.8.9 Undertake capacity building of healthcare workers on appropriate use of antimicrobials
2.8.10 Develop and implement plan for improving facility infrastructure to meet the minimum standards for storage and dispensing of HPT.
2.8.11 Develop and implement a program for strengthening rational use of HPT amongst consumers.
2.8.12 Monitor adherence to clinical guidelines and essential lists in diagnosis, prescribing, procurement and dispensing of HPT.
2.8.13 Review the regulatory framework for promotion including advertisements to cover all HPT as opposed to medicines only.
2.8.14 Enforce controls for promotions including advertising for all HPT.
2.8.15 Undertake sensitization of the media fraternity on acceptable promotions/ advertisements of HPT.
2.8.16 Establish budget line for supporting availability of inventory management tools, guidelines, and SOPs for HPT at all levels.
2.8.17 Develop and implement plan for improving laboratory diagnostic infrastructure to support clinical management.

Strategic Objective 2.9:
Strengthen prompt and safe disposal of HPT waste across all levels of the supply chain

2.9.1 Develop/review policy and guidelines on waste management in line with the devolved health function.
2.9.2 Develop a waste management plan for supplies and other essential HPT.
2.9.3 Establish functional disposal infrastructure in every county.
2.9.4 Establish PPP initiatives for waste management of HPT.
2.9.5 Prepare plan and budgets for disposal of existing HPT waste backlog.

2.9.6 Procure and install incinerators for HPT waste at national and county facilities.

The strengthening of the warehousing, distribution, inventory management and HPT waste management will be undertaken at all levels of the healthcare system and in a way that leverages on collaboration amongst stakeholders. Expected service levels will be clearly defined taking into consideration the expectations of the public and regulatory agencies. The sector will also leverage on technology in enhancing these systems. Systems and tools that support efficient inventory management and data visibility by appropriate stakeholders will be implemented. At the last mile, there will be the provision of appropriate storage space, conditions, and equipment to accord HPT safety and quality and to meet set waste management requirements. The Last Mile Initiative will be scaled up for efficiency and cost effectiveness. To enhance tracking of the interventions in this strategy, the MOH will provide guidance on outsourcing arrangements, as well as define the logistical parameters such as reorder levels, turnaround times, minimum and maximum levels, expected at each level. Further, the cost of supporting the supply chain for HPT in terms of storage, distribution and inventory management will be reviewed on an ongoing basis to inform HPT supply chain budgets and planning.

STRATEGIC PILLAR 3

Enhance and Harness collaboration and partnerships at all levels for effective, coordination resource mobilization and implementation

Coordination amongst players in the HPT supply chain will be enhanced through revitalizing the partnership and coordination organs at all levels. Engagement between the public and private sectors will be harnessed in support of the universal health coverage and towards equitable access for health products and technologies. In line with the obligations of the Constitution of Kenya, 2010, community engagement will be mainstreamed in the implementation of HPT policies with a view to empowering the population on rational use of HPT.

Outcome: Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious, and quality essential HPT.

Key Performance Indicators

1. Number of functional partnerships.
2. Number of public private partnerships forged.
3. Proportion of donor to government funding for essential HPT.
4. Proportion of international indicator price paid by bulk purchasers (KEMSA, MEDS) for a defined basket of essential HPT.

Strategic Objective 3.1:
Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain Strategy

3.1.1 Operationalize the Kenya Health Sector Partnership and Coordination Framework (Finalized in November 2019).
3.1.2 Inaugurate the partnership and coordination structures especially the Health Products and Technologies Interagency Coordinating Committee (ICC).
3.1.3 Undertake regular (quarterly) meetings of the HPT-ICC.

Strategic Objective 3.2:
Develop and implement PPP framework for HPT supply chain

3.2.1 Develop framework for PPP in HPT supply chain.
3.2.2 Establish and promote private sector networks for joint engagement on policy and strategy implementation.
3.2.3 Review mechanisms for effective engagement of non-state actors regularly.
3.2.4 Strengthen dissemination of HPT information including policies, regulations, and guidelines to non-state actors.

Strategic Objective 3.3:
Develop and implement a community engagement framework for effective participation in the implementation process

3.3.1 Develop a community engagement framework for HPT.
3.3.2 Develop community monitoring tools such as score cards for essential HPT.
3.3.3 Establish platforms for community dialogue on HPT matters.
3.3.4 Develop and implement program for community engagement on HPT policy implementation.
3.3.5 Engage civil society networks on HPT supply chain implementation periodically.
3.3.6 Disseminate guidance on HPT embedded in community health strategy.
3.3.7 Undertake community sensitization for empowerment on rational use of HPT.

Strategic Objective 3.4:
Target resource mobilization at national, regional, and international levels

3.4.1 Enhance interagency functional working linkages at national and county level.
3.4.2 Undertake comprehensive mapping of stakeholders and partners for HPT supply chain support.
3.4.3 Establish and maintain collaboration with regional and international organizations pursuing HPT supply chain agenda.
3.4.4 Participate actively in regional cooperation and harmonization efforts relating to regulation and standards setting for HPT.
3.4.5 Collaborate in establishment of regional centres of excellence for HPT issues such as research.
3.4.6 Actively identify and embrace best and promising practices from regional collaboration.

Strategic Objective 3.5:
Establish sustainable financing mechanism for procurement of HPT

3.5.1 Advocate for increased annual health budget to cover HPT procurement and supply chain functions at both national and county government levels and development partners.
3.5.2 Embrace Health insurance and effective HPT reimbursement mechanisms to address OOP expenditure.
3.5.3 Clearly define HPT benefits alongside the UHC benefit package for effective financing of HPT.
3.5.4 Ring-fence HPT budget for procurement at both national and county government level.
3.5.5 Plan for NHIF (and private insurers) to contract private pharmacies to dispense essential HPT.

Strategic Objective 3.6:
Develop a robust mechanism for financial management for HPT supply chain

3.6.1 Track timeliness of disbursement of funds for HPT at all levels.
3.6.2 Align HPT quantification processes to the Annual Planning and Budget Cycle under MTEF.
3.6.3 Develop a clear Resource Allocation Criteria (RAC) for allocation of HPT budgets across counties and within counties.
3.6.4 Strengthen program-based budgeting for HPT.
3.6.5 Capacity build staff on program-based budgeting for HPT.
3.6.6 Improve sharing of information on HPT financing.
3.6.7 Undertake regular audits for HPT to entrench accountability.
3.6.8 Strengthen HPT Financial reporting at all levels for accountability.
3.6.9 Accelerate settlement of outstanding debts related to HPT through payment, negotiations, and write-offs.
3.6.10 Enforce timelines for payment of HPT debts and closely track adherence.

Strategic Objective 3.7:
Undertake structured reforms to improve affordability of health products and technologies

3.7.1 Develop regulatory framework to enable prescriptions by generic names be enforced.
3.7.2 Develop a HPT pricing policy.
3.7.3 Explore opportunities for price regulation with development of a clear regulatory framework.
3.7.4 Provide and publish policy guidance on pricing and mark-ups along the HPT supply chain.
3.7.5 Clarify the reimbursement mechanisms and packages applicable under the UHC program with regards to HPT.
3.7.6 Establish governance structures that support effective monitoring of HPT prices.

3.7.7 Undertake regular surveys for HPT pricing at all levels of the health care system in both private and public sectors and publish findings.
3.7.8 Promote price negotiations through bulk buying for HPT.
3.7.9 Promote pooled procurement of targeted HPT.
3.7.10 Establish a price reference mechanism for HPT.
3.7.11 Maximize the private sector participation in last mile HPT supply chain initiative rolled out by KEMSA and MEDS.

Strategic Objective 3.8:
Strengthen the role of government in leadership, stewardship and coordination of M&E and research for the HPT supply chain

3.8.1 Rationalize and harmonize mechanism for HPT supply chain M&E.
- Finalize and adopt the UHC M&E framework (to incorporate HPT and other elements).
- Establish a function (dedicate a resource) within DHPT that links with the Division of M&E on HPT monitoring and evaluation.
- Clarify and streamline roles and responsibilities for the HPT units at national and county level to support HPT supply chain reporting.
- Strengthen coordination for M&E for HPT at national and county levels.

3.8.2 Improve data management for HPT at national and county level.
- Plan for and implement Regular DQA for HPT.
- Review DQA tools to ensure that they adequately cover HPT indicators.
- Strengthen the capacity of county government M&E unit for review, analysis, and utilization of HPT data.

3.8.3 Strengthen linkage for research and development for HPT.
- Establish a focal point on HPT research within MOH as a first step to build the capacity and ensure effective coordination and priority setting among research institutions/stakeholders.
- Establish Country Health Observatory for assuring comprehensive analysis of Health Information linked with other key research institutions such as KEMRI and universities.
- Enhance investment on research and evidence generation for effective policy and program development.
- Link research and capability for local production of essential HPT to determine level of availability and/or discontinuation as informed by e.g. anti-microbial resistance.

STRATEGIC PILLAR 4

Embrace and adopt Information Communication Technology in all aspects of supply chain for HPT

This strategy recognizes the role of functional information communication technology in the management of supply chain functions at all levels. This strategy advocates for progressive steps towards development of an integrated information system. There will be emphasis on simplicity and coordination at national, program, county, and facility levels and private sector. Therefore, the guidance provided by the Health Information System of the MOH regarding such aspects as design, capabilities, interoperability will be followed whilst appreciating the unique needs for the HPT.

The monitoring and evaluation process and key indicators for supply chain performance shall be carefully defined, with roles and responsibilities for the MOH and other stakeholders. Systems will be established to enable close follow-up of implementation plans at all levels in support of the HPT supply chain. Further, action plans for furthering the research and development as well as the HTA agenda will be implemented.

At the MOH's HPT Division, a dedicated resource will be assigned to deal with HPT information system needs for improved coordination and responsiveness. The health facilities will also be targeted to benefit from electronic systems to improve on efficiency in reporting and utilization of data for HPT planning and decision-making. Health workers at all levels will be empowered with a means to visualize/analyze the data submitted monthly in the national system and ensure continuous availability of life-saving commodities across health facilities.

Outcome: A robust information communication and technology system for HPT supply chain.

Key Performance Indicators

1. Availability of real-time end-to-end visibility of tracer HPT through automation
2. Proportion of institutions (including health facilities) submitting timely and complete HPT reports
3. Proportion of facilities reporting electronically on HPT supply chain

Strategic Objective 4.1:

Regularly review strategies for ICT for HPT supply chain system to accommodate changes in technology

4.1.1 Undertake regular review of strategies for ICT in HPT supply chain.

4.1.2 Ensure that relevant data for decision-making and performance monitoring is collected and reported guided by an established schedule.

4.1.3 Enhance the integration of LMIS considering existing ICT infrastructure.

4.1.4 Enhance the LMIS system to accommodate management of HPT redistribution, waste, and reverse logistics.

4.1.5 Improving LMIS capacity in terms of infrastructure, and human resource capacity.

Strategic Objective 4.2:
Prioritize automation of functions for HPT supply chain at all levels

4.2.1 Develop an HPT supply chain IT implementation plan with clearly defined service level standards.

4.2.2 Define roles and responsibilities for HPT LMIS management across all levels.

4.2.3 Develop protocols for HPT supply chain information.

4.2.4 Dedicate adequate and competent human resources at national and county levels to support the implementation and long-term management of ICT solutions.

4.2.5 Streamline reporting for HPT supply chain to minimize data collection tasks for health providers at facility levels.

4.2.6 Undertake regular supportive supervision to improve data reliability and accuracy.

4.2.7 Develop and implement a comprehensive plan of action for ensuring data visibility for users of the HPT supply chain.

The Ministry of Health, County governments and other stakeholders will scale up their collaborative efforts towards ensuring financial sustainability of the HPT supply chain and viability of the KEMSA revolving fund model. Reforms will be undertaken to ensure that HPT prices are rationalized and made more affordable. Funding for HPT will be mobilized not just for provision of commodities but also for supply chain capacity and infrastructure strengthening, including information technology (IT) and other systems. Transparency and accountability will be enhanced through information sharing, community participation and regular audits to assure effective procurement and distribution activities and value-for-money at large.

4.2.8 Establish HPT logistical coordination committees at county levels charged with the responsibilities of reviewing and analyzing data, addressing challenges, and coordinating information sharing with stakeholders.

4.2.9 Progressively automate facility level procedures, systems, and tools for HPT management with a focus on reliable reporting, efficient ordering an inventory management.

4.2.10 Develop and maintain a mechanism for gradually integrating private health facilities and academic institutions health facilities into the LMIS.

Strategic Objective 4.3:
Improve coordination and systems interoperability

4.3.1 Improve data encryption for HPT HIS.

4.3.2 Improve mechanisms for relaying of HPT data to Kenya Health Information System (DHIS2).

4.3.3 Standardize reporting for all commodities through the national system.

4.3.4 Improve facility-based data transmission from manual forms to electronic.

4.3.5 Coordinate utilization of available HR capacity for maintenance of ICT systems at county level.

4.3.6 Improve budget allocations for supply chain related data reviews.

4.3.7 Undertake quarterly county-led data reviews and annual DQAs for HPT logistics data.

4.3.8 Improve coordination of HPT HIS between programs, and divisions for HPT and HIS at MOH in system development and implementation.

4.3.9 Finalize and roll out system integration framework for HPT.

Strategic Objective 4.4:
Adopt the GS1 Global Standards for track and trace in the supply chain for HPT

4.4.1 Set up a technical working group for GS1 standards implementation.

4.4.2 Identify and train champions for GS1 standards implementation.

4.4.3 Carry out a systems landscape assessment to determine opportunities to leverage on existing systems or integrate new technology.

4.4.4 Develop a traceability approach and IT choreography model that accounts for the roles and capabilities of various trading partners.

4.4.5 Develop an implementation plan covering aspect of identification, location, and data exchange.

The Ministry of Health will develop a strategic and coordinated approach for the adoption of GS1 standards for track and trace, in the management of HPT throughout the country. In doing so, the MOH will incorporate lessons learnt over the years through industry innovations that will lead to better, more efficient supply chain. Implementation and use of global supply chain standards for product identification, location identification, and product master data, and the adoption of these global standards will reduce costs, improve efficiency, and improve the availability of health commodities in Kenya

STRATEGIC PILLAR 5

Scale up Capacity for Research, Local Production and Exploitation of TRIPS Flexibilities for Health Products and Technologies

Local production of health products and technologies will be scaled up over the plan period embracing a value chain approach that recognizes the contribution of various stakeholders while clearly outlining how progress made along the continuum from imports of finished products to establishment of a research- based local HPT industry. The lessons learnt from the recent scale up of local manufacture of PPE and diagnostic kits in response to COVID 19 pandemic will be applied. This agenda will also be pursued in a manner that allows for harmony and reciprocity with policies pursued by other East African Community (EAC) countries.

Additionally, the MOH in collaboration with other stakeholders such as Ministry of Industrialization, Trade, and Enterprise Development, and National Treasury will accelerate the exploitation of TRIPS Agreement Flexibilities towards making HPT available and affordable.

Outcome: A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products

and technologies to the satisfaction of national needs and contributing to industrial development.

Key Performance Indicators

1. Percentage (%) increase in capacity of local pharmaceutical and medical supplies manufacturers.
2. Share of domestic market serviced by locally manufactured pharmaceutical and medical supplies.
3. Proportion of export earnings from pharmaceutical and medical supplies by local manufacturers.
4. Number of local manufacturers fully compliant with WHO GMP standards.
5. Number of essential HPT whose demand can be met in full through local production.
6. Number of TRIPS Agreement Flexibilities invoked.

Strategic Objective 5.1:
Define and provide incentives for Promoting local production of HPT

5.1.1 Revise and Implement the Stepwise GMP Roadmap Program.

- Revise/Update the Stepwise GMP Roadmap.
- Establish a steering committee/ Technical working Group to guide and track implementation of the GMP Roadmap.
- Track implementation of the GMP Roadmap Actions.

5.1.2 Develop a trackable mechanism for enhancing regulatory environment.

- Review pre-licensing requirements, procedures regarding site modification/new buildings guided by layout reviews.
- Establish a risk categorization for companies based on criticality of products, physical sites, and Quality Management Systems; and embed it into the audit procedures.
- Enforce and Report on compliance with risk based minimum licensing standards guided by the roadmap to compliance with WHO GMP standards.
- Undertake annual risk-based audits for compliance with minimum agreed licensing standards.
- Train and build a database of suitable service providers for Corrective Action and Preventive Action (CAPA) development.
- Support pharmaceutical manufacturers to perform gap analysis/CAPA facilitated by the regulatory authority (Pharmacy and Poisons Board).
- Develop a HPT pricing policy that levels the playing field for local manufacturers.
- Develop regulations to enforce use of generic names by prescribers and in all procurement by public health entities.
- Review legislation (Pharmacy and Poisons Act, Cap 244) to support GMP enforcement
- Establish a Bioequivalence Centre through PPP.

5.1.3 Design and implement an enhanced package of incentives to boost local manufacturing capacity for HPT.

- Develop a structured incentive scheme for promoting compliance with WHO GMP.
- Roll out the incentive for compliance with WHO GMP.
- Develop and implement a program for engagement of stakeholders on the GMP roadmap.
- Develop and implement a multi-stakeholder communication strategy for promoting local production and GMP Roadmap agenda.
- Mainstream the Buy Kenya Build Kenya (BKBK) strategy in HPT Supply Chain.

5.1.4 Develop and implement a program for attracting foreign direct investment in local production of HPT.

- Identify and map special economic zones suitable for pharmaceutical industry and mobilization.
- Review market protection approaches for promoting local industry such as import controls and tariff barriers.
- Develop and implement a strategy for affordable financing for local pharmaceutical industries.

5.1.5 Develop human resources for HPT supply chain through relevant education and training.

- Conduct human resources needs assessment for scaling up local production (and implementing GMP Roadmap).
- Review curricula for HPT training to respond to industry needs (ensuring adequate capacity development for implementation of GMP Roadmap).
- Identify and establish resource and training centres for GMP capacity development.

5.1.6 Develop and strengthen research and development platform.

- Develop a platform for knowledge exchange and networking amongst pharmaceutical industrial players.
- Create R&D and Bioequivalence/CRO centre to support local industries.
- Develop an incentive program to promote investment in R&D in HPT.

5.1.7 Formulate and implement incentives for development and production of active pharmaceutical ingredients (APIs) through technology transfer.

- Develop targeted plan for technology transfer and investment that leverages on favourable government investment and industrial policies.
- Undertake mapping to facilitate connections between investors, technology holders and potential recipients, utilizing trusted brokers.
- Develop a program for regulatory reliance and mutual recognition with other African Countries to create larger potential markets and remove hurdles to market access, building on existing economic cooperation efforts.
- Establish and provide funding for centres of excellence to house and amplify technical knowledge.

- Develop a common database of API and raw material sources in collaboration with other African manufacturers.

5.1.8 Consider government investment in local production of strategic HPT.
- Develop strategy and framework for government investment in strategic HPT.
- Undertake investment in local production guided by the developed framework.

Strategic Objective 5.2:
Accelerate the full exploitation of Trade Related Intellectual Property Rights (TRIPS) Flexibilities

5.2.1 Undertake a rapid assessment of the country's readiness to apply the WTO policy tool for TRIPS Agreement flexibilities focusing on manufacturing and exports and then operationalize the tool.

5.2.2 Establish of an interagency committee to facilitate monitoring of implementation of the TRIPS Agreement flexibilities.

5.2.3 Promote utilization of licensing arrangements to improve affordability of HPT.

5.2.4 Promote transparency regarding patent status of existing and new health technologies as well as reporting of TRIPS Agreement flexibilities invoked.

5.2.5 Support the expansion of the locally produced HPT included in the essential HPT lists, and identification of potential products for compulsory licensing (and government use order) through regional pooling mechanisms.

5.2.6 Obtain technical assistance regrading TRIPS Agreement flexibilities from the WTO and WHO.

STRATEGIC PILLAR 6

Strengthen Human Resource Management and Development for HPT supply chain

This strategy acknowledges the urgency to address the human resources and capacity gaps in the HPT supply chain area in the context of devolved governance system. There is need to undertake some assessment of roles and responsibilities for supply chain functions across the public health sector to fully inform any changes, minimize duplications across agencies and levels, clarify reporting responsibilities and formalize routine supply chain practices not captured in job descriptions. Leveraging on recent commitments towards ensuring a high performing supply chain, evidence in the preparatory activities for UHC roll out and COVID-19 response mobilization, there is need to closely follow up the capacity building strategies included in this strategy. The importance of ensuring that there is adequate human capacity, both in terms of quantity and quality, and skills that adequately reflect job requirements cannot be overemphasized. Similarly, improving productivity through regular supportive supervision is necessary.

In enhancing coordination, the need to strengthen capacity of the MOH, Division of HPT, and establish similar units at county governments departments for health to better coordinate the delivery of HPT supply chain functions has been considered. This is critical so as to pull together various important supply chain functions, provide a direct supervisory and structured relationship with the lower levels of the supply chain, strengthen information systems and build data visibility, and emphasize accountability, efficiency and cost-effectiveness, and increase the value of the supply chain for end-users. This will accord the supply chain greater focus on special and critical commodities and emergency response.

Outcome: Adequate human resource for effective management of the health products and technologies.

Key Performance Indicators

1. Number of HPT supply chain staff (e.g. pharmacists) per 10,000 population.
2. Proportion of HPT supply chain positions established and filled in the public health sector.
3. Proportion of academic institutions training HPT supply chain professionals with HPT supply chain module integrated in their curricula.

Strategic Objective 6.1:
Enhance recruitment, retention and rationalize deployment and distribution of human resource for HPT supply chain

6.1.1 Undertake redistribution of HPT supply chain staff to improve equity.
6.1.2 Undertake recruitment of HPT supply chain staff to fill in gaps, in consonance with the HRH Strategic Plan.
6.1.3 Strengthen the supervision and performance assessment of HPT supply chain professionals in the public sector.
6.1.4 Advocate for career progression for HPT supply chain practitioners in the public health sector.

Strategic Objective 6.2:
Review job descriptions for HPT staff to align to HPT functions

6.2.1 Review Schemes of pharmacists, pharmaceutical technologists, nurses, medical engineers, nutritionists, medical laboratory technologists, dentists, COHO and dental technologists, radiology, and supply chain management officers to address HPT supply chain issues holistically and align to practice.
6.2.2 Adopt and disseminate the revised schemes of service.

Strategic Objective 6.3:
Develop and implement a structured and sustainable capacity building program for HPT management

6.3.1 Develop and roll out institution based CPD programs on HPT supply chain.
6.3.2 Formulate and roll out guidelines for on-the-job training (OJT) in HPT supply chain functions.

6.3.3 Enhance capacity of the division of HPT, MOH to coordinate capacity building on HPT supply chain.

6.3.4 Establish and maintain an updated electronic HPT supply chain capacity building database.

6.3.5 Institutionalize in-service training for HPT supply chain for sustainability in view of declining donor funding.

6.3.6 Review pre-service curriculum for health workers to ensure that courses covering principles of managing HPT , procurement, selection, distribution, quality, information management systems assurance and use, are fully integrated.

CHAPTER 4:
IMPLEMENTATION FRAMEWORK

CHAPTER 4

Achievement of the outcomes outlined in this Health Products Technologies (HPT) Supply Chain Strategic plan for the period 2020-2025 requires joint and concerted efforts by various stakeholders across all the levels of the Kenyan Healthcare System – national, county, facilities, and community. The outlined implementation framework not only acknowledges the roles and responsibilities of multi-stakeholders, but also the need for accountability through close monitoring and evaluation of progress made during implementation. Further, it acknowledges that there will be need for decisive and purposeful institutional reforms to create the urgency for and sustain necessary changes for achievement of desired outcomes in the HPT supply chain system.

The overarching challenge of resources (financial, human, and technical) availability remains an important consideration, in view of recent decline in external resources with the country's attainment of lower middle-income status, and pressure from competing priorities. This implementation framework embeds innovative strategies to mobilize and sustain resources, whilst demonstrating best value for money from current and future commitments from both domestic and external partners.

4.1 IMPLEMENTATION FRAMEWORK

This strategy is aligned to the legal and regulatory framework that governs health products and technologies (HPT) as well as supply chain matters in Kenya. The Constitution of Kenya, 2010, is the overarching guide and the other relevant legislations, policy and guidelines have been considered elaborately in the situational analysis. Provisions for revisions where necessary, have been captured in the strategic direction and mapped accordingly in the implementation plan. The implementation framework included in Annex I details the strategic objectives, strategic interventions, annual targets, and responsibilities for implementation.

4.2 IMPLEMENTATION ARRANGEMENTS

Implementation will entail a collaborative, multi-sectoral approach with participation from both public and private sectors, and across the levels of the healthcare system. The public sector at both national and devolved level will play a key role in stewardship guided by the roles assigned as per the Constitution of Kenya, 2010. The national MOH will coordinate provision of technical assistance to the county governments, in additional to leading in setting policies and standards, while the counties will serve as the primary service providers. The private sector will complement provision of HPT as well as support public sector as suppliers and contractors. These will be supplemented by development and implementation partners especially in bridging the resources and technical capacity gaps. This strategy envisages that technical working groups and inter-agency forums for coordination will be revitalized to better serve as platforms for engagement to support joint planning, implementation, reporting and monitoring and evaluation.

Health Products and Technologies Supply Chain in Kenya involves the flow of different product types and the participation of numerous stakeholders in the delivery of those products to fulfil the needs of the citizens and providers who are both individuals and

institutions. Most of the players can be clustered under the following broad categories - producers/manufacturers of HPT (medical and surgical supplies, medical devices and medicines); purchasers (wholesalers, distributors, group purchasers, bulk purchasers, retailers); providers (health facilities, network providers, clinicians, pharmacies); Consumers (Patients); third party agencies (insurance companies); regulatory agencies; government; and development funding and implementation agencies. Interactions among stakeholders based on their interests, that sometimes do conflict with each other and have misaligned incentives making the HPT supply chain complex. The following table provides a summary of some key stakeholders and their envisaged responsibilities in implementation of this strategy.

Table 1 | Stakeholders Responsibility Matrix

Stakeholder	Responsibility
Ministry of Health	Responsible for policy, regulation, standards, and capacity building in the health sector. Responsible for national referral facilities and thus HPT supply chain at that level. MOH will provide appropriate anchorage of the HPT stewardship role for impact and visibility.
County Governments and respective departments of health	Responsible for service delivery in the devolved system of governance including staffing and provision of HPT. County health facilities and the attendant supply chains fall under them. They will steward governance and delivery of HPT supply chain activities at county level as well as collaboration with other stakeholders at county level. Further, they will steward monitoring the implementation of the HPT Policy and strategy at county level.
Other Government line ministries	*The Treasury* has responsibility over the national budget and allocation of funds to ministries like MOH and public agencies such as KEMSA, NQCL, KEMRI, and Regulatory Agencies. These agencies will collaborate in enabling sustainable financing agenda; and development and roll out of incentives for promoting local production of HPT, as well as improving affordability of HPT in the domestic market. *Department of Defence* run health facilities that provide supplies under a parallel supply chain, thus their close collaboration with MOH to reduce duplications and optimize use of resources is expected. *The Ministry of Industrialization, Trade and Enterprise Development* coordinates implementation of the industrialization policy under which local manufacturing of pharmaceuticals is a priority. The ministry will collaborate with MOH and Treasury especially in advancing local production agenda and its contribution to improving availability and affordability of HPT.
National Priority Programs (NASCOP, NMP, NLTD, Immunizations, NCD, RH)	Formulation and implementation of the MOH strategies towards prevention, control and management of specific diseases or conditions of a public health concern nature in Kenya. The programs work with DHPT, MOH in quantification and capacity building, leveraging on the programs' maturity levels; HPT supply chain monitoring with DHPT support; resource mobilization for sustainable financing with regards to the program HPT.
Division of Health Products and Technologies, Ministry of Health	Division at MOH assigned HPT coordination responsibilities for HPT supply chain towards attainment of the objectives of the National Pharmaceutical Policy (NPP)/HPT Policy. The division will enhance its capacity especially in M&E and Policy to deliver the mandate of policy guidance, and coordination of HPT supply chain implementation monitoring at all levels.
HPT Medicines and Therapeutics Committees (National and County)	Responsible for production and review of Standard Treatment Guidelines, Essential HPT lists, and formularies in consultations with health practitioners in the HPT supply chain. These committees will be revitalized for greater visibility, and to effectively support agenda for rational HPT use.
Health Products and Technologies Inter-Agency Coordination Committee	High level consultative forum for HPT matters with membership from MOH, development partners, public agencies, counties, private sector, and civil society.

Stakeholder	Responsibility
National Drug Authority (the Pharmacy and Poisons Board)	Responsible for regulation of quality and use of HPT and ensuring that HPT in the Kenyan market meet the standards for safety, efficacy, and quality. It regulates professionals by setting standards for practice and implementation, providing post-market surveillance, and regulating aspects of the promotion of rational HPT use including prescribing and dispensing, and improving access to accurate and appropriate product information. The capacity will be enhanced to monitor implementation of all suppliers and health commodities (manufacturers for good manufacturing practice [GMP] compliance, and wholesalers for adherence to good warehousing and distribution practices). Further, collaboration with manufacturers, importers, and distributors in the development of incentives and sanctions to support self-regulation of quality will be enhanced.
National Quality Control Laboratories (NQCL)	Undertakes quality control testing on HPT during production, and importation and eventual supply to the final consumers and after (post-market surveillance and pharmacovigilance). The capacity will be strengthening, and structured collaboration with PPB and other quality control laboratories such as MEDS and DARU built.
Regulatory Bodies for Health Professionals	Regulates professionals by setting standards for practice and implementation. These agencies will work with PPB /KFDA and MOH in advancing rational HPT use objective as well as enforcing standards towards improving affordability, availability and quality of HPT. It also supports strengthening of the in-service training curriculum to integrate HPT supply chain aspects.
Professional Associations	Self-regulation of professionals by setting standards for practice and implementation. These institutions will collaborate with regulatory agencies and MOH in advancing rational HPT use objective as well as enforcing standards towards improving affordability, availability, and quality of HPT. They will also support strengthening of HPT supply chain capacity through their in-service training programs.
Kenya Medical Supplies Authority (KEMSA)	Procures, stores, and distributes health commodities to all public health facilities within the country. It is expected to work more closely with facilities to strengthen inventory management capacity, good storage practices and minimization of waste. Further, its governance systems will be strengthened for greater transparency and accountability, improved supplier performance and ultimately affordable HPT in the market.
National Hospital Insurance Fund (NHIF)	Provides insurance coverage for registered members and ensures that they receive needed quality health services. It will support clarification and implementation of sustainable financing mechanisms for HPT under the UHC framework as well as the use of regulatory mechanisms to manage the prices of HPT more effectively.
Public Procurement Regulatory Authority (PPRA)	Provides oversight in public procurement in line with the PPAD Act, 2015. Undertakes periodic market surveys to provide guiding prices for application during procurement processes. The agency will work with MOH to address concerns over HPT prices while complying with PPAD Act, 2015, in addition to supporting enforcement of regulations for HPT for fairness and to support the rationale for investments in quality production.
Private Sector including private hospitals, pharmacies, pharmaceutical manufacturers, and wholesalers	Complement the public sector supply chain as suppliers and providers of service. Critical contribution to the availability, affordability, and quality objectives of the HPT supply chain.
Faith-based Organizations	Critical implementer of national health policies including HPT; provides health services to a substantial portion of the Kenyan population especially in the traditional hard to reach areas. Generally, aligns policies to the national ones and has signed MOU with the GOK.
Civil Society	Advocates for the interests of the beneficiaries of HPT supply chain activities. Critical accountability partner in strengthening community participation in HPT supply chain planning and decision-making at all levels.
Teaching and Research Institutions	Serving as centres of excellence in training of health and allied staff in collaboration with the MOH and MOE. Undertake research to support HPT supply chain (production and operations). Providing evidence to guide policy setting.
Health Facilities (National and County)	Use HPT for clients. Also carry out reporting, ordering, storage, and procurement functions.

Stakeholder	Responsibility
Development Partners	Provision of financial and technical support for HPT Supply Chain.
Implementation Partners (local and international)	Provision of technical support for HPT Supply Chain

4.3 FINANCIAL RESOURCE ESTIMATES AND MOBILIZATION

4.3.1 Resource Requirements for HPT Strategy Implementation

The HPT strategy was costed from a health systems perspective using the Activity-Based Costing (ABC) approach. The costs of ingredients needed to achieve the planned targets were estimated by considering the quantities of inputs, frequency in which inputs were required, and unit costs of relating to the inputs for specific activities included in the implementation plan. Total costs were then determined through summation at output, objective and pillar level. In estimating costs, evidence was collected primarily from the secondary sources, and then complemented with key informants and expert opinions.
A total of KES 464 billion is required for implementation of this HPT supply chain strategy 2020-2025. Figure 4.1 summarises the estimated costs by strategic plan implementation years.

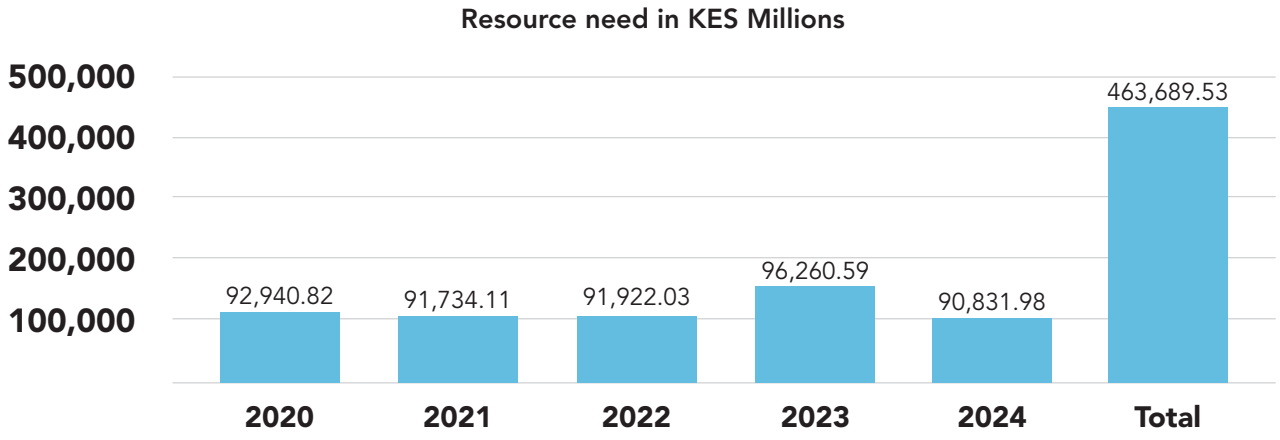

Figure 4.1 | Resource Requirements in KES Millions for the five years

In terms of resource requirements estimates for the six pillars of this strategy, pillar two on establishment and sustenance of a robust HPT selection, quantification, procurement, distribution system, is projected to take the bulk of the resources at 98%. Under SP 2, the estimates include KES 452 Billion being the resource requirements for procurement of various HPT guided by current quantification reports for EMMS for counties and national referral facilities, HPT special programs namely HIV, Malaria, TB, RH/FP and Vaccines. The EMMS and HIV commodities, NCDs, Vaccines and Malaria are projected to account for 39.4% ,40.4%, 7%, 6% and 4.1% respectively. The quantification estimates are presented in table 4.2 and figure 4.2 below.

Table 4.1 | Cost estimates for the HPT Supply Chain Strategy by Strategic Pillars (in KES Millions)

Strategic Pillars (SP1-SP6)	20/21	21/22	22/23	23/24	24/25	KES M	%
SP 1: Enhance Capacity for Governance, Regulation and Quality Assurance	342.3	254.4	147.7	121.0	121.0	**986.4**	**0.2%**
SP 2: Establish and Sustain a robust HPT Product Selection Quantification Procurement and Distribution System	91,541.8	89,705.6	89,635.1	94,428.6	89,178.3	**454,489.5**	**98.0%**
Strategic Pillars (SP1-SP6)	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**KES M**	**%**
SP 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation	350.5	342.4	289.8	275.6	263.8	**1,522.1**	**0.3%**
SP 4: Embrace and Adopt Information Communication Technology in all aspects of supply chain for HPT	560.0	81.9	564.6	39.2	20.9	**1,266.7**	**0.3%**
SP 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities	78.5	97.2	69.1	186.6	38.3	**469.6**	**0.1%**
SP 6: Strengthen Human Resource Management and Development for HPT supply chain	67.8	1,252.5	1,215.7	1,209.6	1,209.6	**4,955.3**	**1.1%**
Grand Total	**92,940.8**	**91,734.1**	**91,922.0**	**96,260.6**	**90,832.0**	**463,689.5**	**100.0%**

Table 4.2 | Estimates for HPT Quantifications Cost for the HPT Strategy (KES Millions)

Quantification areas	2020	2021	2022	2023	2024	Total	Percent
EMMS/ National Referrals	35,665	35,665	35,665	35,665	35,665	**178,325**	**39.4%**
HIV	35,000	36,945	36,945	36,945	36,945	**182,779**	**40.4%**
TB	748	1,344	1,334	1,334	1,334	**6,094**	**1.3%**
Malaria	6,327	1,936	1,997	6,855	1,571	**18,686**	**4.1%**
RH/FP	1,502	1,611	1,611	1,611	1,611	**7,946**	**1.8%**
Vaccines	5,400	5,400	5,400	5,400	5,400	**27,000**	**6.0%**
NCDs	6,336	6,336	6,336	6,336	6,336	**31,678**	**7.0%**
Total	**90,978**	**89,237**	**89,287**	**94,145**	**88,861**	**452,507**	**100.0%**

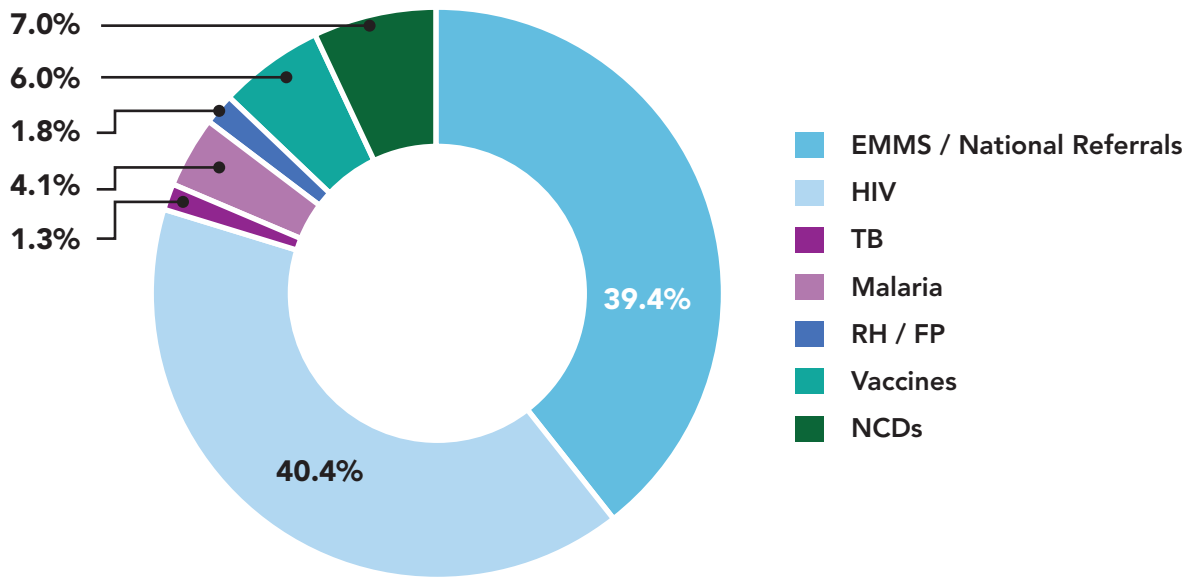

Figure 4.2 | Quantification Cost estimates for the HPT Supply Chain Strategy

4.3.2 Estimate of Available Resources

Resources available for implementation of this HPT supply chain strategy were estimated with the aid of data from secondary sources and corroborated with interviews with MOH officials building on the understanding of how the health systems and services have been financed in the past. Domestic funding is primarily from public sources based on government financial commitments as documented in national and county government budgets and medium term expenditure plans. Commitments relating to government counterpart funding to strategic programs were also factored in. External funding is based on current known commitments by both multilaterals and bilateral development partners. Projections for year four and five estimates are based on the first three years. The available resource estimate of KES 182 Billion indicates that that there is a significant contribution expected from external funders especially for priority public health programs.

Table 4.3 | Estimates and Projections for Financial Resources Available by Funding Source (KES Millions)

Funding Source	2020	2021	2022	2023	2024	Total	Percent
Total Domestic	14,659.0	15,015.4	15,657.8	16,347.1	17,087.9	**78,767.3**	**43.2%**
External Funding	19,962.6	20,671.7	20,869.5	21,069.2	21,069.2	**103,642.2**	**56.8%**
Total	**34,621.6**	**35,687.2**	**36,527.2**	**37,416.3**	**38,157.1**	**182,409.5**	**100%**

4.3.3 Funding Gap Analysis

The financing gap was estimated by generating the difference between the total estimated resource requirements and the estimated available resources for each of the years of this strategic plan. This financing gap estimated at KES 281 Billion indicates the additional resources that need to be mobilized from both domestic and external sources in support of full implementation of the interventions in this strategic plan. The analysis of funding gap estimates by implementation year is presented in figure 4.3 and Table 4.4 that follows.

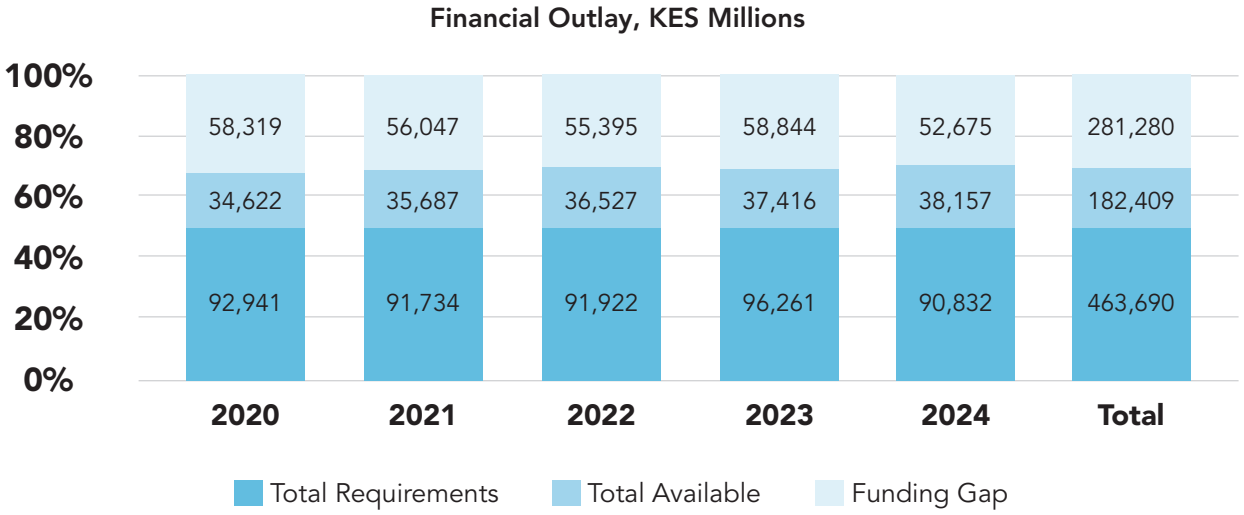

Figure 4.3 | Financial gap analysis for HPT Strategy (KES millions)

Table 4.4 | Financial Gap Analysis for HPT Supply Chain Strategic Plan (KES Millions)

Funding	2020	2021	2022	2023	2024	Total
Total Resource Requirements	92,941	91,734	91,922	96,261	90,832	**463,690**
Total Available Resources Estimates	34,622	35,687	36,527	37,416	38,157	**182,409**
Funding Gap Estimate	**58,319**	**56,047**	**55,395**	**58,844**	**52,675**	**281,280**

4.3.4 Bridging the Funding Gap

Bridging the funding gap is critical to ensure that implementation of the strategic interventions in this strategy is not hampered by lack of resources. As such, resource mobilization is considered a critical pillar in this strategy - strategic pillar 3 envisages that collaboration and partnerships will be harnessed at all levels for effective mobilization and implementation. There is need for innovative strategies to mobilize and sustain funding including from non-traditional sources.

A two-pronged approach will be adopted. First, by ensuring that resources projected as available are made available and prudently utilized. Advocacy and lobbying will be undertaken with the legislative arms of county governments and national government for increased budget allocations. Additionally, partners and stakeholders will be identified, mapped, and continuously engaged for support towards implementation of this strategy.

Second, appreciating that a critical ingredient to the continuity of support is transparency and accountability - implementation of this strategy will be closely monitored to ensure that resources are optimally utilized and that funders receive accountability reports that are accurate and timely. An annual report documenting the progress of achievements made in implementation of this strategic plan will be prepared and shared with stakeholders to sustain commitment.

4.4 RISK MANAGEMENT

The effects of uncertainty on the achievement of the objectives contained in this HPT Supply Chain Strategy is acknowledged at this stage. The strategy therefore builds in, as a good governance practice, measures to provide reasonable assurance that significant risks will be identified, documented and monitored in a way that enables management at the various levels to make informed decisions and timely take actions; opportunities will be maximized whilst managing associated risks; and the objectives set out will be achieved. This strategy has provided some preliminary identification of risks that the MOH will need to elaborate, assess in terms of impact and likelihood of occurrence, and develop a risk management plan to facilitate close monitoring and management of known and emerging risks.

4.5 PERFORMANCE MANAGEMENT

A performance framework to facilitate the successful implementation of this strategic plan has been adopted. In particular, the framework provides a basis for setting performance targets that are aligned to the overall sector targets. The expectation is that the targets (alongside the stated strategic objectives and strategic interventions) will be incorporated into not only the strategic plans but also operational plans for the assigned institutions. This cascade will facilitate effective implementation as well as monitoring and evaluation of performance. Further, reliance will be made on existing systems of managing performance such as the performance contracting system for ministries, departments, and public agencies, and the staff performance appraisal reporting system for public service. The

implementation matrix and the performance matrix included Annexes 1 and 2 will facilitate implementation tracking and monitoring.

4.6 MONITORING AND EVALUATION

4.6.1 Coordination and alignment

The overall responsibility for coordination of monitoring and evaluation of this strategic plan (and its attendant strategies as unpacked at different levels) is assigned to the Ministry of Health's function responsible for Health Products and Technologies – currently the Division of HPT. This strategy embeds a monitoring and evaluation framework that links the inputs, activities/interventions, outputs, and outcomes of HPT Supply chain initiatives. Further, it also guided by the ethos of accountability in the Constitution of Kenya, 2010, Health Act, 2017, Kenya Health Policy, and the Kenya National Pharmaceutical Policy.

The framework is aligned to already defined targets that are set out in key policy documents, international commitments, as well as overall strategic plan for the health sector. It considers County governments-defined targets to the extent possible.

The Ministry of Health, in collaboration with partners, will invest in building the capacity of M&E for HPT Supply Chain while ensuring there is alignment with the overall Health Sector M&E vision. Dedicated resources responsible for coordinating monitoring progress of indicators for HPT Supply Chain will be domiciled at the function responsible for HPT.

4.6.2 Data Collection and Review

Data to monitor the strategic plan will be obtained from routine and non-routine sources. Data collection for M&E indicators will utilize both qualitative and quantitative methods and, as much as possible, employ standardized data collection tools and analysis techniques. Most data will be collected routinely, and any survey-based indicators will be collected at baseline, midterm and at the end of implementation of the strategic plan. Data collection tools to be utilized include the KHIS, LMIS, HRIS, Commodity Management Systems and Financial Systems. This strategy anticipates that the relevant reporting tools will be made available at all required levels of health system to facilitate harmonized and complete reporting. Supportive supervision will be strengthened to enhance appropriate use of reporting tools and review of collected data for quality.

4.6.3 Data analysis, reporting and dissemination

MOH, County governments, and partners will leverage on electronic and manual systems to strengthen the data management processes from collection, collation, storage, analysis, reporting, dissemination, and use. To streamline data collection and reporting, the MOH and county governments will work towards, scale up of the ICT infrastructure and EMR deployment with enhanced interoperability of electronic systems at service delivery points, county and sub-county levels. Quarterly reports of performance will be prepared to facilitate progress review against the targets included in this strategic plan. Use of data repositories will be encouraged to enhance quality of data review and use. Data dissemination will be conducted through the various learning and leadership forums for HPT supply chain

management with a view to improving decision-making and ultimately improving the health outcomes.

Routine and non-routine data analysis will be conducted against the identified indicators and targets in the performance management framework. The sector shall compare standards given in the objectives with the actual results and any variance identified will inform remedial actions.

The MOH will coordinate provision of technical support and facilitate capacity building in M&E for HPT supply chain in liaison with the county governments and partners. Capacity building will target, amongst other areas, data analytics, interpretation, and presentation for the HPT supply chain. This will improve the ability of health care workers to understand question formulation, identification of data sources, use of data analytics and geospatial tools and development of information products.

4.6.4 Core Indicators

The indicators adopted for tracking this strategy are based on the consideration and consensus that monitoring will be undertaken at input, process, output, and outcome levels. The logic followed is that investment made in the HPT supply chain through inputs and processes will yield outputs and outcomes that are desired in the health sector. The inputs and processes will be tracked through the milestones identified in the implementation matrix as well as the select indicators that relate to interventions such as human resources, policies/legislation. Process indicators included in the performance management matrix will track initiatives such as training/capacity building interventions, coordination meetings and TRIPS flexibilities invoked, that translate to outputs and in turn result to outcomes in form of increased coverage and quality. Ultimately the outcomes will yield longer term impact in form of reduction in disease burden, reduction in mortality, increased life expectancy and wellbeing.

The key performance indicators are highlighted under each pillar in the strategic direction and elaborated in Annex II - detailed table of indicators with definitions, data source, reporting frequency, level of measurement, responsibility, baseline values, and targets. The M&E logical framework for this HPT Strategy is presented in Table 4.5 that follows.

Table 4.5 | HPT Supply Chain Strategy M&E Logical Framework

	Inputs	Process	Output	Outcome
	• Policies, laws, guidelines, manuals • Warehousing infrastructure • Technology • Finances • Data • Equipment • Products	• Quality control • Drug information service • Enforcement • Registration of products • Training • Quantification, Product Selection • Warehousing and distribution • Partnerships • HPT Curriculum review • Supervision • HPT Supply chain audits and DQAs • Resource mobilization • Reporting	• Number trained • Quality improvement • Data Utilization in decisions • Availability of HPT • Availability of funding • Availability of staff	• Service coverage • Adverse reactions • Equity • Affordability • Access • Responsiveness
Indicators	• Legislation formulated • Oversight/ Governance structures established • Warehouses set up • Guidelines formulated	• Number of products registered • Laws reviewed • Partnerships established • Number of joint HPT supply chain audits	• Functional MTCs • Quality control pass rate • Compliance with STG, eHPT lists • Forecast accuracy • Order fill rate • Proportion of facility with stock-outs • Turnaround time • Proportion of funding for essential HPT • Proportion of facilities reporting electronically • End to end visibility	• Average availability of essential HPT • HPT Staff per 10,000 • API manufacturers • Proportion of exports of HPT by WHO compliant manufacturers • Affordability index
Data Sources	Administrative Sources • Databases, stores records, financial registers		• Facility Assessments (service availability and readiness assessments • Bi-annual supply chain capacity and performance assessment • KHIS • LMIS	Population based surveys, Health Facility assessments
Analysis and Synthesis	Data Reviews, Data Quality Assessments, Operational Research Studies, Use of Research Results, Assessments for progress of implementation of HPT Supply Chain strategy, Estimates and Projections			
Communication and Use	Scheduled and *ad hoc* Reporting, Data Review Meetings, Stakeholders Forums, Information Products such as newsletters, bulletins & dashboards, blogs			

4.6.5 Research, Evaluation and Learning

Measurements Learning and Accountability approach will be embraced by ensuring that measurement of results is accompanied by identification of lessons learned to drive continuous improvement of the HPT supply chain and enhance accountability.

Information and data use will be enhanced using research and evaluation. Operation research studies will be carried out on an annual basis to determine the extent to which the objectives of this strategy are met. This strategy envisages that this will be one of the main areas for collaboration between implementation agencies at national and county level, with academic and research institutions. The products generated from these operational studies will be applied to inform planning and decision-making, including shaping corrective actions where necessary. A joint HPT Supply Chain Capacity and Performance assessment will be undertaken every two years to assess the progress made towards achievement of the objectives in this strategy and document the maturity status.

In terms of evaluation, the strategic plan will be evaluated at midterm and end term. Evaluation will take into consideration measures of relevance, efficiency, effectiveness, sustainability, and impact.

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APPENDICES

APPENDIX I - GLOSSARY OF KEY TERMS

Term	Meaning
Good Distribution Practices	Practices used to deliver health products and technologies to their users that ensures product integrity and cost effectiveness.
Good Manufacturing Practices	Practices for making the best and affordable health products and technologies.
Essential Medicines and Health Supplies	Medicines, medical devices, health supplies, laboratory supplies and consumables, medical and laboratory equipment.
Essential Health Products and Technologies (EHPT)	Those products that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. EHPT are always intended to be available within the context of a functioning health system in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
Fill rate	An item-based measurement that shows the percentage of demand that was met at the time they were placed. Fill rate only measures what happens when demand occurs.
Health Products and Technologies	Health products and technologies: The application of organized knowledge and skills in the form of medicines, devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of lives.
Health Worker	Any person working in the health system who hold a health care qualification recognized by the Government of Kenya. The health workforce constitutes those persons recruited primarily for health and related service provision and management who have undergone a defined, formally recognized training programme.
Lead Time	The length of time between the decision to purchase an item and its actual addition to stock.
Medicine/ Pharmaceutical product	The terms are used interchangeably and may include all or some of the following: medicines, vaccines, medical devices, traditional and complementary medicines, health supplies, blood, biological products and other related healthcare products.
Pharmacovigilance	The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem, after they have been licensed for use, especially to identify and evaluate previously unreported adverse reactions. The aims of pharmacovigilance are to enhance patient safety in relation to the use of medicines and to support public health programmes by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.
Post-Market Surveillance	The process of monitoring the safety of drugs once they reach the market, after the successful completion of clinical trials. The primary purpose for conducting post-market surveillance is to identify previously unrecognized adverse effects as well as positive effects. Post-market-surveillance activities including maintenance of products' authorization/registration through variations or renewals, regular inspections of manufacturers, wholesalers/distributors/retailers, quality control testing, and pharmacovigilance.

Term	Meaning
Reverse logistics	The requirement to plan the flow of surplus or unwanted material or equipment back through the supply chain after meeting customer demand.
Supply chain	The total sequence of processes, within a single or multiple enterprise environments, that enable customer demand for a product or service to be satisfied.
Supply-Chain Management (SCM)	Organization of the overall processes that enable the transformation of raw materials or products into finished goods and their timely distribution to meet customer demand.
Trade-Related Aspects of Intellectual Property Rights (TRIPS)	Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the World Trade Organization that sets down standards for forms of intellectual property that member nations should apply in order to provide strong protection to global intellectual property rights.
Universal Health Coverage (UHC)	Ensuring that everyone who needs health services is able to get them without undue financial hardship.
Warehouses	All central level warehouses involved in or supporting the national health supply chain including KEMSA and MEDS.

APPENDIX II - LIST OF CONTRIBUTORS

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1.	Dr. Josphat Mbuva	MOH, Head of HPT Division – Team Lead
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61	Wesley Ogara	MOH, HIS Division
62	Zeinab Gura	MOH - HRH

APPENDIX III - KEY INFORMANTS

	National Ministry of Health	
1	Ministry of Health (MOH) Directorates Heads	Directors
2	Division of HPT	Head, Division of HPT

	MOH Programs	
3	RMNCAH	Program Manager
4	NASCOP	Program Manager
5	Malaria	Program Manager
6	TB	Program Manager
7	NCD (Cancer)	Program Manager
8	Vaccines	Program Manager
9	National Public Health Laboratories	Head, NPHL
10	National Blood Transfusion Services (NBTS)	Head, NBTS
11	Kenya Medical Supplies Authority	CEO, KEMSA
12	Pharmacy and Poisons Board (PPB)	CEO, PPB
13	National Quality Control Laboratories (NQCL)	CEO, NQCL
14	Council of Governors	CEO, Council of Governors (and Chair of the Health Committee)

	County Governments	
15	Chair of County Executive Committee Members (CECM) for Health Caucus	Chair of Forum
16	Chair of Chief Officers for Health (COH) Caucus	Chair of Forum
17	Chair of caucus for County Directors for Health (CDH) Services	Chair of Forum
18	Chair of Caucus for County Pharmacists / County HPT Supply Chain Coordinators	Chair of Forum
19	Chair of Caucus for County Heads of Supply Chain/ Directorates of Procurement	Chair of Forum

	National Referral Facilities	
20	Kenyatta National Hospital (KNH)	CEO, Head of Pharmacy
21	Moi Referral and Teaching Hospital (MTRH)	CEO, Head of Pharmacy
22	Kenyatta University Teaching and Referral (KUTRH)	CEO, Head of Pharmacy
23	Mathari Hospital	Medical Superintendent
24	National Spinal Injury	Medical Superintendent

	County Facilities	
	Level 5 facilities	
25	Mombasa, Coast Referral Hospital	Medical Superintendent
26	Kisii Teaching and Referral Hospital	Medical Superintendent
	Level 4 facilities	
27	Wajir	Medical Superintendent
28	Siaya	Medical Superintendent
29	Kakamega	Medical Superintendent
	Level 3 facilities	
30	Kitui	Facility in-charge
31	Nyeri	Facility in-charge
32	Narok	Facility in-charge
	Level 2 facility	
33	Lamu	Facility in-charge
34	Nandi	Facility in-charge
35	Marsabit	Facility in-charge

	Other Ministries and Public Agencies	
36	Ministry of Industrialization	Director of Industrialization
37	KenInvest	CEO, KenInvest
38	Kenya Bureau of Standards (KEBS)	CEO, KEBS
39	University of Nairobi	Dean, Faculty of Pharmacy
40	Kenyatta University	Dean, Faculty of Pharmacy
41	Kenya Medical Training College (KMTC)	CEO, KMTC
42	The National Treasury	Director of Supply Chain
43	Ministry of Devolution	Director of Intergovernmental Relations
44	Public Procurement Regulatory Authority (PPRA)	CEO, PPRA
45	Kenya Institute of Supplies Management (KISM)	CEO, KISM
46	ICT Authority	CEO, ICT Authority

	Faith-based Organizations	
47	Mission for Essential Drugs Supply (MEDS)	CEO, MEDS
48	CHAK (Christian Health Association of Kenya)	CEO, CHAK
49	KCCB (Kenya Conference of Catholic Bishops)	Executive Secretary, Catholic Health Commission
50	SUPKEM Health Association	Executive Secretary, SUPKEM

	Private Sector	
51	Kenya Health Federation (KHF)	CEO, KHF
52	Kenya Association of Pharmaceutical Industry (KAPI)	CEO, KAPI
53	Federation of Kenya Pharmaceutical Manufacturers (FKPM)	CEO, FKPM
54	Kenya Association of Manufacturers	CEO, KAM
54	ASCM Partners (Coca Cola, Bidco, Safaricom)	Director, ASCM

	Health Professional Associations	
55	Pharmaceutical Society of Kenya	CEO, PSK
56	Kenya Pharmaceutical Association	CEO, KPA
57	Kenya Medical Association	CEO, KMA

	Regulatory Bodies	
58	Kenya Health Professionals Oversight Authority (KHPOA)	CEO, KHPOA
59	Nursing Council	CEO, NCK
60	KMPD Council	CEO, KMPD
61	Laboratory Technologists Council	CEO, LT Council
62	Pharmacy and Poisons Board	CEO, PPB
63	Clinical Officers Council	CEO, COC

	Development Partners	
64	World Bank	Health Lead
65	WHO	HPT Supply Chain Lead
66	UNFPA	HPT Supply Chain Lead
67	UNICEF	HPT Supply Chain Lead
68	Bill and Melinda Gates Foundation	HPT Supply Chain Lead
69	USAID	HPT Supply Chain Lead
70	The Global Fund	Fund Portfolio Manager, Kenya

	Implementation Partners	
71	Chemonics (Afya Ugavi)	Chief of Party, Afya Ugavi
72	Bill & Melinda Gates ARC Program	Director, ARC
73	Management Sciences for Health	Director, MTAPS
74	Clinton Foundation (CHAI)	Director, CHAI
75	HealthStrat	Director, HealthStrat

ANNEXES

ANNEX 1 – IMPLEMENTATION PLAN WITH COST ESTIMATES

Strategic Pillar 1: Enhance Capacity for Governance, Regulation and Quality Assurance																								
	Outcome	***An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious Health Products and Technologies by the population***																						
	Strategic Objectives *Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices* *Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy* *Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimize efficiency* *Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship* *Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems* *Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program* *Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects* *Strategic Objective 1.8: Institutionalize Health Technology Assessment (HTA) in HPT management*																						
	Strategic Interventions	**Milestones**	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
1.1	**Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices**		MOH, DPHT																					
1.1.1	Enact legislation for a single regulatory body for regulation of HPT in line with Health Act, 2017	Legislation enacted	MOH																					16.1
1.1.2	Review PPDA Act, 2015 - Regulations for 2020 to accommodate multiple awards for HPTs	Legislation reviewed	PPRA																					7.2
1.1.3	Review Health Laws (Ammendment) Act , 2019 to provide for alternatives sourcing of HPTs in the event of inadequacies from KEMSA	Legislation reviewed	MOH, KEMSA																					9.64
1.1.4	Develop regulations to facilitate enforcement of prescribing and dispensing by generic/INN names	Regulations in place	MOH																					26.65
1.1.5	Develop guidelines for professional and ethical conduct by manufacturers,wholesalers, and retailers	Guidelines in place	MOH, KFDA/PPB, KHF																					33.41
1.2	**Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy**		MOH, DPHT																					

Strategic Pillar 1: Enhance Capacity for Governance, Regulation and Quality Assurance																									
	Outcome	***An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious Health Products and Technologies by the population***																							
	Strategic Objectives *Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices* *Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy* *Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimize efficiency* *Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship* *Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems* *Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program* *Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects* *Strategic Objective 1.8: Institutionalize Health Technology Assessment (HTA) in HPT management*																							
	Strategic Interventions	**Milestones**	**Responsibility**	**Timeframe**																					***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**					
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4		
1.2.1	Undertake mid-term review of the National Pharmaceutical Policy (NPP) 2012 to inform the review process/development of the new HPT policy	NPP Mid Term Review done	MOH, DHPT																						4.8
1.2.2	Review NPP 2012/Develop new HPT policy	Revised HPT Policy																							20.13
1.2.3	Develop and disseminate HPT pricing guidelines	HPT Pricing guidelines developed and disseminated	MOH, DHPT																						15.33
1.2.4	Develop and disseminate guidelines for promoting local production of HPT	Local Production guidelines in place	MOH, DHPT																						15.33
1.2.5	Develop and disseminate guidelines for promoting full exploitation of TRIPS Flexibilities	TRIPS guidelines in place	MOH, DHPT																						15.33
1.2.6	Develop and disseminate policy guidelines for linking of HPT quantification, procurement and the MTEF planning and budgeting cycle	Quantification & MTEF linkage guidelines in place	MOH, DHPT																						15.33
1.2.7	Develop and disseminate guidelines on HPT supply chain information availability (transparency) detailing minimum standards for information availability to stakeholders to enhance public participation	Transparency guidelines in place	MOH, DHPT																						15.33
1.3	**Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimise efficiency**		MOH, DPHT																						

Strategic Pillar 1: Enhance Capacity for Governance, Regulation and Quality Assurance																									
	Outcome	***An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious Health Products and Technologies by the population***																							
	Strategic Objectives *Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices* *Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy* *Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimize efficiency* *Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship* *Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems* *Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program* *Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects* *Strategic Objective 1.8: Institutionalize Health Technology Assessment (HTA) in HPT management*																							
	Strategic Interventions	**Milestones**	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
1.3.1	Establish a robust oversight mechanism for KEMSA	KEMSA oversight enhanced	MOH																					6.36
1.3.2	Establish a robust oversight mechanism for PPB/KFDA	KFDA/PPB oversight enhanced	MOH																					9.06
1.3.3	Establish a robust oversight mechanism for NHIF	NHIF oversight enhanced	MOH																					6.36
1.3.4	Establish mechanism for collaboration and joint working for regulatory bodies tackling HPT related issues (Professionals Regulatory bodies, KEBS, KVB, KHPOA)	Mechanism in place	MOH, DHPT																					6.36
1.3.5	Establish a system for monitoring and reporting on compliance with existing regulations	Monitoring system in place	MOH																					6.36
1.3.6	Carry out periodic review and gap analysis of existing regulations and enforcement capacity and performance	Review undertaken	MOH																					25.44
1.4	**Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship**		MOH, DPHT																					
1.4.1	Elevate the division of HPT to directorate level with clear mandate, organization structure, functions and establishment	HPT division elevated	MOH																					1.6
1.4.2	Progressively operationalise the directorate to the desired staffing level and capacity	Directorate capacity enhanced	MOH																					

Strategic Pillar 1: Enhance Capacity for Governance, Regulation and Quality Assurance																							
	Outcome	***An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious Health Products and Technologies by the population***																					
	Strategic Objectives *Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices* *Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy* *Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimize efficiency* *Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship* *Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems* *Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program* *Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects* *Strategic Objective 1.8: Institutionalize Health Technology Assessment (HTA) in HPT management*																					
	Strategic Interventions	**Milestones**	**Responsibility**	**Timeframe**																			***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
1.4.3	Provide support to county departments of health (CDOH) to establish HPT governance structures	County HPT units in place	MOH, DHPT, CDOH																					40.26
1.4.4	Develop a capacity building program for the staff of the MOH HPT function guided by the staffing assessment	Capacity building program rolled out	MOH, HRD																					14.2
1.5	**Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems**		MOH, DPHT																					
1.5.1	Provide for the appropriate establishment of NQCL in the KFDA legislation	NQCL reesyablished appropriately	MOH																					
1.5.2	Develop a protocol for information sharing with key stakeholders and otherHPT quality assurance laboratories	Protocol for information sharing in place	MOH																					1.59
1.5.3	Enhance capacity (numbers, skills and technology) of NQCL to undertake full complement of HPT quality assurance tests	Capacity enhanced	MOH, KFDA, NQCL																					5.4
1.5.4	Establish regional analytical laboratories for HPTs	Regional labs established	MOH, KFDA, NQCL																					
1.5.5	Support NQCL to continously upgrade and maintain WHO and ISO 17025 prequalification certification scheme	Certification status maintained	NQCL																					
1.5.6	Expand the research capability of NQCL to offer full range of HPT tests	Expanded research capacity	NQCL																					

Strategic Pillar 1: Enhance Capacity for Governance, Regulation and Quality Assurance																							
	Outcome	***An enabling and supportive legislative and regulatory framework and system that assures availability and use of safe and efficacious Health Products and Technologies by the population***																					
	Strategic Objectives *Strategic Objective 1.1: Review and harmonize Health Products and Technologies supply chain related legislations and regulations for effective regulation of products, human resources, premises and practices* *Strategic Objective 1.2: Review national pharmaceutical policy of 2012 /develop new HPT policy* *Strategic Objective 1.3: Enhance oversight functions for bodies charged with financing, procurement & supply and regulation of HPT to optimize efficiency* *Strategic Objective 1.4: Strengthen governance structures for HPT at MOH and County Departments of Health (CDOH) for effective leadership and stewardship* *Strategic Objective 1.5: Strengthen NQCL's professional semi-autonomy in line with relevant legislation and its quality assurance systems* *Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program* *Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects* *Strategic Objective 1.8: Institutionalize Health Technology Assessment (HTA) in HPT management*																					
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				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
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1.5.7	Strengthen collaboration linkages with select institutions and programs	Collaborations in place	MOH, KFDA, NQCL																					0.96
1.5.8	Enhance use of technology in quality management including maintenace of database for HPT tests undertaken	Technology use enhanced	NQCL																					
1.6	**Strategic Objective 1.6: Strengthen Pharmacovigilance and Post Market Surveillance Program**		MOH, DPHT																					
1.6.1	Gazette pharmacovigilance(PV) regulations/rules	Regulations gazetted	KFDA/PPB																					
1.6.2	Undertake regular and sustained dissemination (including sensitisation) of the pharmacovigilance guidelines to counties and other stakeholders	Dissemination done	MOH, DHPT; CDOH																					25.96
1.6.3	Update the PV reporting system (PvERS) to include all HPT	Updated PvERS	KFDA/PPB																					3.32
1.6.4	Prepare and disseminate quarterly PV reports	Quarterly PV reports prepared and shared	KFDA/PPB																					146.95
1.6.5	Appoint members the PV/PMS Advisory Committee	Committee in place	KFDA/PPB																					
1.6.6	Develop and gazette PMS regulations	PMS regulations in place	KFDA/PPB																					1.6
1.6.7	Review/Update the PMS strategy	PMS strategy revised	KFDA/PPB																					2.4

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1.6.8	Develop guidelines, SOPs and job aids for PMS	Guidelines, SOPs and Job aids in place	KFDA/PPB																					2.4
1.6.9	Develop a sustainable capacity building program for PV and PMS for the all the key stakeholders (PPB, KEMSA, NQCL, MEDS, MOH, CDOH, health facilities)	Capacity building program rolled out	KFDA/PPB																					1.59
1.6.10	Establish budget lines for PV and PMS at all levels	Budget line established	MOH																					
1.6.11	Develop an integrated data management system/platform for PMS that enables tracking all the quality aspects of health products in Kenya	integrated data management system/platform for PMS in place	KFDA/PPB																					3.4
1.7	**Strategic Objective 1.7: Optimize the contribution of Traditional and Alternative Medicines while protecting the public from any negative effects**		MOH, DPHT																					
1.7.1	Finalize and disseminate the new TAM Policy	TAM policy finalised	MOH																					12.93
1.7.2	Finalise the development of TAM Bill and enactment of TAM legislation and regulations	Legislation in place	MOH																					8.9
1.7.3	Operationalise various components of TAM regulations e.g. registration, PV, PMS of TAM products	TAM regulations effected	MOH																					100.8
1.7.4	Develop a database for TAM products, practitioners and practices	TAM database in place	KFDA/PPB																					3.4

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1.7.5	Develop and roll out TAM research guidelines	Research guidelines developed	MOH, DTAM; PPB																					13.96
1.7.6	Develop and implement an incentive scheme for promoting research in TAM	Incentive scheme in place	MOH, DTAM; PPB																					9.16
1.7.7	Sensitize Traditional and Alternative Medicine practitioners on quality control testing	Practictioners sensitised	MOH, DTAM; NQCL																					3.08
1.7.8	Establish mechanism for information and knowledge exchange on TAM with other countries	Mechanism in place	MOH																					11.7
1.7.9	Develop a national TAM pharmacopeia to support quality and safety testing of TAM products	TAM pharmacopeia in place	MOH, NQCL																					14.11
1.8	**Strategic Objective 1.8: Institutionalise Health Technology Assessment (HTA) in HPT management**		MOH, KEMRI																					
1.8.1	Develop an overarching Health Technical Assessment policy for Kenya to cover all HPTs	HTA policy formulated	MOH, KEMRI																					22.57
1.8.2	Develop a national HTA roadmap	HTA roadmap in place	MOH, KEMRI																					7.125
1.8.3	Build capacity for HTA at national government HPT supply chain agencies and county governments	Capacity building program rolled out	MOH, CDOH																					10.24
1.8.4	Increase stakeholder involvement at both levels of government throughout the HTA process to help capture and improve the create value and applicability of HTAs	Stakeholders engaged on HTA	MOH, CDOH																					12.28

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1.8.5	Undertake surveys to assess utilization of HTA in HPT Supply Chain planning and decision making such as pricing and, market authorization for HPT	HTA surveys conducted	MOH, CDOH																					250

Strategic Pillar 2: Establish and Sustain a robust HPT Product Selection Quantification Procurement and Distribution System																								
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2.1	**Strategic Objective 2.1: Ensure that all health products and technologies for the public health system are responsive to the priority needs in line with concept of essential HPT**		MOH, DHPT																					
2.1.1	Establish a system for regularly reviewing priority health needs and revising the essential HPT lists	System for review of essential lists in place	MOH, DHPT																					7.95
2.1.2	Complete development and validation of essential medical devices list	Devices list finalised	MOH, DHPT																					15.68
2.1.3	Disseminate the essential HPT lists for medicines (KEML), medical supplies (KEMSL) and medical devices (non-pharmaceutical supplies and medical equipment) KEMDL	Essential HPT lists disseminated	MOH, DHPT; CDOH																					14.31
2.1.4	Plan for review, update and dissemination of essential HPT lists every two years (next one due in 2022) to ensure relevance and usefulness	Plan in place	MOH, DHPT; CDOH																					100.62
2.1.5	Review, update and disseminate standard clinical and referral guidelines	Guidelines reviewed and disseminated	MOH, DHPT; CDOH																					17.54
2.1.6	Develop a national formulary for all listed essential medicines and selected medical supplies	Formulary in place	MOH, DHPT; CDOH																					47.8
2.1.7	Undertake surveys on adherence to essential lists for HPTs in product selection across all levels	Survey undertaken	MOH, DHPT; CDOH																					2.82

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2.1.8	Carry out studies on adherence to the standard treatment guidelines	Study conducted	MOH, DHPT; CDOH																					2.82
2.1.9	Avail the finalized the essential HPT lists and STGs on MOH and County websites for increased accessibility	Published lists for eHPT	MOH, DHPT; CDOH																					-
2.2	**Strategic Objective 2.2: Establish and sustain a system for timely and accurate quantification of health products and technologies at all levels of the health system**																							
2.2.1	Enhance coordination and capacity for quantification of HPT at national and county, and facilities for effective and reliable of HPT		MOH, CDOH																					-
2.2.1.1	*Clarify roles and responsibilities for quantification of laboratory supplies and medical devices*	*Quantification Roles clarified*	MOH, CDOH																					-
2.2.1.2	*Disseminate guidelines for HPT quantification and forecasting to national programs, county governments and health facilities*	*Guidelines disseminated*	MOH, CDOH																					10.7
2.2.1.3	*Develop a harmonized capacity building program for forecasting and quantification of counties and facilities incorporating all priority program aspects and essential lists*	*Harmonised capacity building program*	MOH, CDOH																					12.0

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2.2.1.4	*Share quantification tools and outputs amongst stakeholders (through the coordination committees at national, county and facility levels) leveraging on HPT/Commodity Management Information System (CMIS)*	*Tools shared*	MOH, CDOH																					5.9
2.2.1.5	*Revitalize the role of HPT Technical Working Groups in quantification*	*Quantification TWG functional*	MOH, CDOH																					
2.2.1.6	*Review pre-service and in-service courses related to HPT supply chain to ensure they contribute to forecasting and quantification*	*Curriculum reviewed*	MOH, CDOH, KHPOA, Universities																					19.1
2.2.1.7	*Automate forecasting and quantification functions at all levels ultimately integrating with the DHIS system*	*Quantification automated*	MOH, CDOH, KEMSA																					12.7
2.2.1.8	*Undertake training of HPT supply chain staff on the use of automated forecasting and quantification tools*	*Training conducted*	MOH, CDOH, KEMSA																					28.6
2.2.2	Develop and/or review where necessary, quantifications for all essential HPT for the strategic plan period	quantifications reviewed																						
2.2.2.1	*Undertake quantification exercise for all essential HPTs for 3 years, based on consumption or services data and stock on hand supported by automated information systems at all levels applying a bottom up approach*	quantifications reviewed	MOH, CDOH, KEMSA																					9.5
2.2.2.2	*Review the HPT forecasts annually and make necessary adjustments*	quantifications reviewed	MOH, CDOH, KEMSA																					19.1

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2.2.3	Closely track quantification process at all levels	Quantification report	MOH, CDOH, KEMSA																					
2.2.3.1	*Develop and disseminate a comprehensive calendar for HPT quantification process that is aligned to the national MTEF budget and planning cycle*	Circular on quantification issued	MOH, DHPT																					127.2
2.2.3.2	*Ensure all counties complete HPT quantification in time through close follow up*	Quantification report	MOH, DHPT																					71.6
2.2.3.3	*Enhance accuracy of HPT demand forecasting through structured review process*	Accuracy review report	MOH, DHPT																					1.0
2.2.3.4	*Undertake monthly review of stock reports against quantifications undertaken to track performance targets by HPT categories and make corrective actions*	Monthly reviews done	MOH, CDOH																					636.0
2.2.3.5	*Track adherence of procurement to county HPT supply plans and make adjustments as appropriate*	quarterly procurement plan review	CDOH																					265.0
2.3	**Strategic Objective 2.3: Ensure essential Health Products and Technologies are sourced in a cost effective and efficient manner**																							
2.3.1	Update and harmonize policies, legislation, guidelines and manuals to support effective procurement of HPT	Harmonised policies and manuals	MOH, CDOH																					

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2.3.1.1	*Align the KEMSA Act,2013; KISM Act,2007; Health Laws (Amendments) Act, 2019 and Pharmacy and Poisons Act, Cap 244 to support HPT supply chain procurement*	Revised legislation	MOH, KEMSA, CDOH																					31.9
2.3.1.2	*Revise Health Laws (Amendment) Act, 2019 to facilitate acquisition of HPTs by county government and public health facilities with regard to products that KEMSA may be unable to supply.*	Revised legislation	MOH, KEMSA, CDOH																					31.9
2.3.1.3	*Update the Public Health Sector Procurement Manual (2009)*	Revised manual	MOH, KEMSA, CDOH, PPRA																					25.5
2.3.1.4	*Finalize the essential lists for HPTs and ensure reconciliation with lists maintained by KEMSA*	Reconciled lists	MOH, KEMSA, CDOH, PPRA																					
2.3.1.5	*Harmonize the KEMSA Procurement Policy with PPAD Act, 2015 Regulations of 2020*	Harmonised policy	MOH, KEMSA, CDOH, PPRA																					12.7
2.3.1.6	*Disseminate the emergency HPT Supply Chain framework*	Emergency framework disseminated	MOH, CDOH, PPRA																					14.3
2.3.1.7	*Operationalize multiple awards regulation*	Multiple awards operationalised	MOH, KEMSA, CDOH, PPRA																					3.6
2.3.2	Strengthen coordination of HPT procurement and procurement planning functions to minimize fragmentation/duplication																							
2.3.2.1	*Enhance collaboration between the HPT Coordination units at County governments and the County Supply Chain Functions*	Reduced fragmentation	MOH, CDOH																					28.6

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2.3.2.2	*Strengthen coordination of HPT procurement and procurement planning functions to minimize fragmentation/duplication*	Reduced fragmentation	MOH, CDOH																				
2.3.2.3	*Establish County HPT Coordination Units with clear structures, mandate and staffing*	HPT coordination units set up	MOH, CDOH																				
2.3.2.4	*Undertake joint planning for HPT procurement between partners and government with transparent scheduling*	Joint planning held	MOH, CDOH																				31.8
2.3.2.5	*Revitalize the procurement coordination role for the Division of HPT at MOH; and replicate the arrangements at county governments*	HPT coordination units set up	MOH, CDOH																				
2.3.2.6	*Develop an integrated multi-year procurement financing plan with clear stakeholder commitments*	Multi year plan in place	MOH, CDOH																				
2.3.3	Undertake capacity strengthening in procurement of HPTs																						
2.3.3.1	*Establishment of a technology based system for monitoring utilization of essential lists across public and private sectors*	System in place	MOH, CDOH																				
2.3.3.2	*Develop a program for strengthening capacity of the sector in HPTs contracts management, in collaboration with the private sector*	Capacity program in place	MOH, KHF																				12.7

Strategic Pillar 2: Establish and Sustain a robust HPT Product Selection Quantification Procurement and Distribution System																								
	Outcome	***An effective and efficient system that ensures quality assured HPT, that are responsive to priority needs, are available and accessible to the population at the point of use.***																						
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				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
2.3.3.3	*Undertake reforms on integrated commodity security and pipeline monitoring coordinated by DHPT*	Pipeline monitoring undertaken and reported	MOH, CDOH																					
2.3.3.4	*Establish a national platform for integrated procurement and information management systems*	Platform in place	MOH																					9.5
2.3.3.5	*Strengthen MOH oversight for public procurement systems (KEMSA, MEDS etc.) to eliminate redundancies, duplications and bottlenecks to enhance efficiency*	HPT coordination capacity strengthened	MOH																					
2.3.3.6	*Strengthen the capacity and position of the MOH, HPT Division for effective oversight of HPT across the sector*	HPT coordination capacity strengthened	MOH																					
2.3.3.7	*Strengthen the procurement capacity for HPT sector, especially with regards to vendor performance management, use of technology, openness and fair competition*	Improved vendor performance management	MOH																					
2.3.4	Improve transparency in procurement of HPT																							
2.3.4.1	Publish lists of registered suppliers in the public sector at national, county and facility levels	List published	MOH, CDOH																					
2.3.4.2	Promote information exchange and sharing on HPT procurement in private and public sector	Information exchange enhanced	MOH, KHF																					

Strategic Pillar 2: Establish and Sustain a robust HPT Product Selection Quantification Procurement and Distribution System																							
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2.3.4.3	Advocate for the use of essential lists and formularies for HPTs in the private sector	Use of eHPT lists enhanced	MOH, KHF																				
2.3.4.4	Improve information sharing regarding tendering processes including justification for splitting tenders	Transparency enhanced	MOH, KEMSA																				
2.3.5	Procure drugs and medical supplies	Procurement undertaken																					452,507
	Drugs, medical and surgical supplies, blood transfusion commodities, laboratory reagents, specialized medical imaging and consumable supplies, specialized medical commodities and supplies		MOH, CDOH, KEMSA																				
2.3.6	Enhance reforms in procurement including supplier development to improve affordability of HPT	Improved affordability																					
2.3.6.1	*Promote and advocate for pooled procurement of HPTs in the private sector*	Improved affordability	MOH, KEMSA																				6.0
2.3.6.2	*Establish robust price reference framework mechanism for HPTs for both public and private sectors*	Price reference framework in place	MOH, KEMSA																				6.0
2.3.6.3	*Strengthen supplier performance monitoring capacity*	Supplier performance management improved	MOH, CDOH, KEMSA																				
2.3.6.4	*Establish an electronic based system of measuring and managing supplier performance*	e-vendor management system	MOH, CDOH, KEMSA																				

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2.3.6.5	*Expand utilisation of the supplier monitoring tool approved by PPRA*	PPRA tool adopted	MOH, PPRA																					10.7
2.3.6.6	*Harmonize and simplify systems and status for exemption from custom duties and taxes for HPTs*	System in place	MOH, Treasury																					3.6
2.3.6.7	*Improve monitoring of custom clearance process for efficiency and effectiveness (timeliness and allocation of funds)*	custom clearance improved	MOH																					17.8
2.4	**Strategic Objective 2.4: Improve storage capacity for HPT at national, county and facility levels**																							
2.4.1	Undertake rationalized infrastructure improvement for storage and handling especially at level 3 & 2 facilities	Infrastructure improved	MOH, CDOH																					
2.4.2	Develop and disseminate storage and inventory SOPs	SOPS disseminated	MOH, CDOH																					10.1
2.4.3	Enforce Good HPT inventory management practices	Improved storage practices	MOH, PPB																					
2.4.4	Institute a capacity strengthening program for staff on HPT inventory management	Improved storage practices	MOH DHPT																					
2.4.5	Enhance the involvement of private sector in provision of leased storage spaces (National/central stores in the Counties)	Improved storage capacity	MOH, KHF																					0.5
2.4.6	Expand KEMSA's storage capacity in Nairobi and regional depots	Improved storage capacity	MOH, KHF																					

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2.5	**Strategic Objective 2.5: Embrace ICT in warehousing and distribution**																						
2.5.1	Scale up use of technology in stores management/records	Improved ICT use	MOH, KEMSA																				
2.5.2	Digitize records where possible in a phased approach e.g. starting with all level 5-4, then 3-2	Improved ICT use	MOH, KEMSA																				
2.5.3	Set up systems for end to end visibility of HPTs in the supply chain	End to end visibility	MOH, KEMSA																				
2.5.4	Improve visibility of goods on transit	End to end visibility	MOH, KEMSA																				
2.5.5	Automate proof of delivery documentation	Automated proof of delivery	MOH, KEMSA																				
2.6	**Strategic Objective 2.6: Strengthen the distribution network to the last mile based on sector needs**																						
2.6.1	Advocate for increased resources/funding for distribution of HPT	Increased funding	MOH, CDOH																				4.5
2.6.3	Expand KEMSA distribution network (beginning with Kisumu and Mombasa regional depots)	Expanded distribution network	KEMSA, MOH																				21.6
2.6.4	Establish mechanisms for intra and inter-county distribution to reduce wastage	Reduced wastage	KEMSA, MOH																				4.5

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2.6.5	Set up robust system for reverse logistics	Robust reverse logistics in place	KEMSA, MOH																					4.5
2.7	**Strategic Objective 2.7: Improve order processing and receipt management**																							
2.7.1	Streamline pick, pack and ship processes at KEMSA with additional order assembly lines	Order assembly lines added	KEMSA																					
2.7.2	Maximize on integration of orders for both programs and EMMS	Integration in place	KEMSA																					
2.7.3	Develop guidelines for Reverse logistics management	Guidelines developed	MOH, KEMSA																					1.6
2.7.4	Develop order scheduling plan with, and for Counties	Order scheduling in place	MOH,CDOH																					9.9
2.7.5	Develop, communicate and execute a county ordering schedule to reduce order turnaround time	Order scheduling in place	MOH, KEMSA																					31.4
2.7.6	Sensitize health facility staff and third party logistics firms (3TPL) on good receipt practices	Staff sensitised	KEMSA, KHF, MOH																					
2.8	**Strategic Objective 2.8: Develop and implement a comprehensive rational use program for HPT**																							
2.8.1	Establish and operationalise medicines and therapeutic committees(MTC) at national, county and hospital level	Functional MTCs	MOH DHPT; CDOH																					12.2

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2.8.2	Establish NMTC as a statutory committee and covering all HPTs	NMTC statute in place	MOH																					2.7
2.8.3	Support county and hospital MTCs to carry out operational research on management and use of HPT	Functional MTCs	MOH																					56.7
2.8.4	Strengthen inventory management for HPT at all levels	Improved inventory management	MOH, KEMSA																					
2.8.5	Develop and implement a program for strengthening rational use of HPT amongst health workers	Rational HPT use program in place	MOH, DHPT																					9.5
2.8.6	Develop a National HPT formulary	Formulary in place	MOH, DHPT																					
2.8.7	Advocate for review of preservice training curriculum for health workers to incorporate elements of HPT management (selection, quantification, procurement, inventory management, prescribing and dispensing)	Curriculum reviewed	MOH																					6.4
2.8.8	Review and develop an integrated in-service curriculum for capacity building of health workers on HPT management	Curriculum reviewed	MOH																					6.4
2.8.9	Undertake capacity building of healthcare workers on appropriate use of antimicrobials	Capacity program in place	MOH, CDOH																					9.5
2.8.10	Develop and implement plan for improving facility infrastructure to meet the minimum standards for storage and dispensing of HPTs	Infrastructure improved	MOH, CDOH																					

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2.8.11	Develop and implement a program for strengthening rational use of HPT amongst consumers	Rational HPT use program in place	MOH, CDOH																					6.4
2.8.12	Monitor adherence to clinical guidelines and essential lists in diagnosis, prescribing, procurement and dispensing of HPTs	Improved adherence	MOH, DHPT																					
2.8.13	Review the regulatory framework for promotion including advertisments to cover all HPTs as opposed to medicines only	Regulations reviewed	KFDA/PPB																					
2.8.14	Enforce controls for promotions including advertising for all HPTs	Enforcement enhanced	KFDA/PPB																					
2.8.15	Undertake sensitization of the media fraternity on acceptable promotions/advertisements of HPTs	Sensitisation conducted	KFDA/PPB																					
2.8.16	Establish budget line for supporting availability of inventory management tools, guidelines and SOPs for HPTs at all levels	Budget line established	MOH, CDOH																					
2.8.17	Develop and implement plan for improving laboratory diagnostic technology to support clinical management	Plan in place	MOH, CDOH																					
2.9	**Strategic Objective 2.9: Ensure correct disposal of HPT waste across all levels of the supply chain**																							

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2.9.1	Develop/review policy and guidelines on disposal of wastes including hazardous waste in line with the devolved health function	Policy and guidelines reviewed	MOH, CDOH																					12.0
2.9.2	Develop a waste management plan for supplies and other essential HPT	Plan in place	MOH, CDOH																					
2.9.3	Establish functional disposal sites in every county	Disposal sites set up	MOH, CDOH																					
2.9.4	Establish PPP initiatives for waste management of HPT	PPP initiatives established	MOH, KHF																					
2.9.5	Prepare plan and budgets for disposal of existing HPT waste backlog	Waste backlog cleared	MOH, CDOH																					8.0
2.9.6	Procure and install incinerators for HPT waste at national and county facilities	Incinerators installed	MOH, CDOH																					

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																							
	Outcome	***Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious and quality essential HPT***																					
	Strategic Objectives *Strategic Objective 3.1: Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain strategy* *Strategic Objective 3.2: Maximize engagement between public and private sectors for effective implementation* *Strategic Objective 3.3: Enhance community participation for effective implementation* *Strategic Objective 3.4: Mobilize national regional and international support* *Strategic Objective 3.5: Rally for resources for procurement of quality HPT and systems in a sustainable fashion* *Strategic Objective 3.6: Develop and sustain systems for efficient utilization of funding for HPT supply chain* *Strategic Objective 3.7: Undertake structured reforms to improve affordability of health products and technologies* *Strategic Objective 3.8: Strengthen government stewardship in coordination of M&E and research for the HPT supply chain*																						
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3.1	**Strategic Objective 3.1: Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain strategy**																							
3.1.1	Operationalize the Partnership and Coordination Framework (Finalized in November 2019)	Partnership structures established	MOH																					-
3.1.2	Inaugurate the partnership and coordination structures especially the Health Products and Technologies Interagency Coordinating Committee (ICC)	Partnership structures established	MOH																					0.1
3.1.3	Undertake regular (quarterly) meetings of the HPT - ICC	HPT ICC meetings held	MOH																					0.9
3.2	**Strategic Objective 3.2: Develop and implement PPP framework for HPT supply chain**																							
3.2.1	Develop framework for PPP in HPT supply chain	Framework in place	MOH, KHF																					
3.2.2	Establish and promote private sector networks for joint engagement on policy and strategy implementation	Networks established & operationalised	MOH, KHF																					0.5

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3.2.3	Review mechanisms for effective engagement of private sector actors regularly	Networks established & operationalised	MOH, KHF																					3.2
3.2.4	Strengthen dissemination of HPT information including policies, regulations and guidelines to private sector providers	Information products developed and disseminated	MOH, KHF																					4.2
3.3	**Strategic Objective 3.3: Develop and implement community engagement framework for effective participation in the implementation process**																							
3.3.1	Develop and implement program for community engagement on HPT policy implementation	Community engagement report	MOH, CDOH																					9.6
3.3.2	Establish platforms for community dialogue on HPT matters	Community engagement report	MOH, CDOH																					2.7
3.3.3	Develop community monitoring tools such as score cards for essential HPT	Score cards developed	MOH, CDOH																					2.4
3.3.4	Engage civil society networks on HPT supply chain implementation periodically	Community engagement report	MOH, CDOH																					20.8

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																						
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3.3.5	Disseminate guidance on HPT embedded in community health strategy	Community engagement report	MOH, CDOH																					4.2
3.3.6	Undertake community sensitization for empowerment on rational use of HPT	Community engagement report	MOH, CDOH, PPB																					13.7
3.4	**Strategic Objective 3.4: Target resource mobilization at national, regional and international levels**																							
3.4.1	Enhance interagency functional working linkages at national and county level	Interagency committee meetings held	MOH, CDOH																					6.3
3.4.2	Undertake comprehensive mapping of stakeholders and partners for HPT supply chain support	Mapping done	MOH DHPT																					0.1
3.4.3	Establish and maintain collaboration with regional and international organizations pursuing HPT supply chain agenda	Collaborations report	MOH DHPT																					117.0
3.4.4	Participate actively in regional cooperation and harmonization efforts relating to regulation and standards setting for HPT	Collaborations report	MOH, PPB																					117.0
3.4.5	Collaborate in establishment of regional centers of excellence for HPT issues such as research	Collaborations report	MOH, PPB, KEMRI																					9.0

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																						
	Outcome	***Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious and quality essential HPT***																				
	Strategic Objectives *Strategic Objective 3.1: Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain strategy* *Strategic Objective 3.2: Maximize engagement between public and private sectors for effective implementation* *Strategic Objective 3.3: Enhance community participation for effective implementation* *Strategic Objective 3.4: Mobilize national regional and international support* *Strategic Objective 3.5: Rally for resources for procurement of quality HPT and systems in a sustainable fashion* *Strategic Objective 3.6: Develop and sustain systems for efficient utilization of funding for HPT supply chain* *Strategic Objective 3.7: Undertake structured reforms to improve affordability of health products and technologies* *Strategic Objective 3.8: Strengthen government stewardship in coordination of M&E and research for the HPT supply chain*																					
		Milestones	**Responsibility**	**Timeframe**																			***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
3.4.6	Actively identify and embrace best and promising practices from regional collaboration	Regional ollaborations report	MOH, PPB																					234.0
3.5	**Strategic Objective 3.5: Establish sustainable financing mechanism for procurement of HPT**																							
3.5.1	Advocate for increased health budget to cover HPT supply chain functions at both National and county government levels	HPT budget increased	MOH, CDOH																					32.3
3.5.2	Ring-Fence HPT budget at both national and county government level	HPT budget increased	MOH, CDOH																					6.5
3.5.3	Embrace Health insurance and effective HPTs reimbursement mechanisms to address OOP	HPT funding increased	MOH, NHIF, KEMSA																					0.1
3.5.4	Plan for NHIF(and private insurers) to contract private pharmacies to dispense essential HPT	Contracting arrangements in place	MOH, NHIF, CDOH																					0.1
3.5.5	Develop and implement guidelines for cost recovery for HPTs	Cost recovery guidelines in place	MOH, NHIF, CDOH																					4.8
3.5.6	Clearly define HPTs benefits alongside the UHC benefit package for effective financing of HPTs	HPT benefit package defined	MOH, NHIF, CDOH																					4.8

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																							
	Outcome	***Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious and quality essential HPT***																					
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				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
3.6	**Strategic Objective 3.6: Develop a robust mechanism for financial management for HPT supply chain**																							
3.6.1	Track timeliness of disbursement of funds for HPT at all levels	Disbursements report	MOH DHPT																					0.9
3.6.2	Align HPT quantification and forecasting processes to the Annual Planning and Budget Cycle under MTEF	Quantification linked to MTEF cycle	MOH DHPT																					0.9
3.6.3	Develop a clear Resource Allocation Criteria (RAC) for allocation of HPT budgets across counties and within counties	RAC revised	MOH DHPT																					2.4
3.6.4	Strengthen program based budgeting for HPT	PBB with HPT elaborated	MOH DHPT																					6.3
3.6.5	Improve sharing of information on HPT financing	PBB with HPT elaborated	MOH DHPT																					0.5
3.6.6	Capacity build staff on program based budgeting for HPTs	PBB with HPT elaborated	MOH DHPT																					21.3
3.6.7	Undertake regular audits for HPTs to entrench accountability	HPT focused audits done	MOH, CDOH																					69.5
3.6.8	Strengthen HPT Financial reporting at all levels for accountability	HPT Financial Reports extracted	MOH, CDOH																					69.5

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																							
	Outcome	***Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious and quality essential HPT***																					
	Strategic Objectives *Strategic Objective 3.1: Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain strategy* *Strategic Objective 3.2: Maximize engagement between public and private sectors for effective implementation* *Strategic Objective 3.3: Enhance community participation for effective implementation* *Strategic Objective 3.4: Mobilize national regional and international support* *Strategic Objective 3.5: Rally for resources for procurement of quality HPT and systems in a sustainable fashion* *Strategic Objective 3.6: Develop and sustain systems for efficient utilization of funding for HPT supply chain* *Strategic Objective 3.7: Undertake structured reforms to improve affordability of health products and technologies* *Strategic Objective 3.8: Strengthen government stewardship in coordination of M&E and research for the HPT supply chain*																						
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					Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
					Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
3.6.9	Accelerate settlement of outstanding debts related to HPTs through payment, negotiations and write offs	Outstanding debts resolved	MOH, CDOH																					0.1
3.6.10	Enforce timelines for payment of HPT debts and closely track adherence	Outstanding debts resolved	MOH, CDOH																					0.5
3.7	**Strategic Objective 3.7: Undertake structured reforms to improve affordability of health products and technologies**																							
3.7.1	Develop regulatory framework to enable prescriptions by generic names be enforced	Regulations in place	MOH																					2.4
3.7.2	Develop a HPTs pricing policy	Policy developed	MOH																					24.0
3.7.3	Explore opportunities for price regulation with development of a clear regulatory framework	Regulations in place	MOH																					9.6
3.7.4	Provide and publish policy guidance on pricing and mark-ups along the HPT supply chain	Policy developed	MOH																					7.2
3.7.5	Clarify the reimbursement mechanisms and packages applicable under the UHC program with regards to HPT	Reimbursement mechanisms clarified	MOH, NHIF																					0.5
3.7.6	Establish governance structures that support effective monitoring of HPT prices	HPT Pricing Committee established	MOH, CDOH																					13.9

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																							
	Outcome	***Collaborations and partnerships in health products and technologies supply chain yielding synergies, and addressing gaps to safe, efficacious and quality essential HPT***																					
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				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
3.7.7	Undertake regular surveys for HPT pricing at all levels of the health care system in both private and public sectors and publish findings	Surveys undertaken	MOH, CDOH, KHF																					212.5
3.7.8	Promote price negotiations through bulk buying for HPTs	Price reduction achieved	MOH, CDOH, KEMSA																					0.7
3.7.9	Promote pooled procurement of targeted HPTs	Price reduction achieved	MOH, CDOH, KEMSA																					0.7
3.7.10	Establish a price reference mechanism for HPTs	Price reference mechanism in place	MOH, KEMSA, PPB																					0.7
3.7.11	Maximize the private sector participation in last mile HPT supply chain initiative rolled out by KEMSA and MEDS	Last mile scaled up	MOH, CDOH, KHF																					0.7
3.8	**Strategic Objective 3.8: Strengthen government stewardship in coordination of M&E and research for the HPT supply chain**																							
3.8.1	Rationalize and harmonize mechanism for HPT supply chain M&E	Improved coordination of M&E for HPT	MOH DHPT																					
3.8.1.1	Finalize and adopt the UHC M&E framework (to incorporate HPTs and other elements)	M&E framework revised	MOH DHPT																					2.4
3.8.1.2	Establish a function (dedicate a resource) within DHPT that links with the Division of M&E on HPT monitoring and evaluation.	Resource deployed	MOH DHPT																					

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																								
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				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
3.8.1.3	Clarify and streamline roles and responsibilities for the HPT units at national and county level to support HPT supply chain reporting	M&E framework revised	MOH, CDOH																					18.5
3.8.1.4	Strengthen coordination for M&E for HPT at national and county levels	Improved coordination of M&E for HPT	MOH, CDOH																					13.9
3.8.2	Improve data management for HPT at national and county levels	HPT SC data quality improved	MOH, CDOH																					34.6
3.8.2.1	Plan for and implement Regular DQA for HPT	HPT SC data quality improved	MOH, CDOH																					34.6
3.8.2.2	Review DQA tools to ensure that they adequately cover HPT indicators	HPT SC data quality improved	MOH, CDOH, KHF																					2.4
3.8.2.3	Strengthening of the capacity of county government M&E unit for review, analysis and utilization of HPT data necessary	HPT SC data quality improved	MOH, CDOH																					13.9
3.8.3	Strengthen linkage research and development for HPT	Research dissemination reports	MOH, KEMRI, Universities																					0.2
3.8.3.1	Establish a focal point on health research within MOH as a first step to build the capacity and ensure effective coordination and priority setting among research institutions/stakeholders	Research coordination improved	MOH																					

Strategic Pillar 3: Harness collaboration at partnerships at all levels for effective resource mobilization and implementation																							
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	Strategic Objectives *Strategic Objective 3.1: Harness synergies and opportunities from collaborations and partnerships for effective implementation of the HPT Supply Chain strategy* *Strategic Objective 3.2: Maximize engagement between public and private sectors for effective implementation* *Strategic Objective 3.3: Enhance community participation for effective implementation* *Strategic Objective 3.4: Mobilize national regional and international support* *Strategic Objective 3.5: Rally for resources for procurement of quality HPT and systems in a sustainable fashion* *Strategic Objective 3.6: Develop and sustain systems for efficient utilization of funding for HPT supply chain* *Strategic Objective 3.7: Undertake structured reforms to improve affordability of health products and technologies* *Strategic Objective 3.8: Strengthen government stewardship in coordination of M&E and research for the HPT supply chain*																						
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				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
3.8.3.2	Establish Country Health Observatory (as per EAC) for assuring comprehensive analysis of Health Information linked with other key research institutions such as KEMRI and universities	Observatory established	MOH																					0.1
3.8.3.3	Enhance investment on research and evidence generation for effective policy and program development	Research funding increased	MOH, KEMRI, Universities																					0.8
3.8.3.4	Link research and capability for LPP of essential HPT to determine level of availability and/or discontinuation (as in anti-microbial resistance)	Research disemination reports	MOH, KEMRI, Universities																					0.5
3.8.4	Enhance supportive supervision dedicated for HPTs at national and county level	Supervision undertaken	MOH, CDOH																					212.5
3.8.5	Enhance capacity in resources for HPT Division for M&E	HPT Monitoring capacity improved	MOH, CDOH																					148.8

Strategic Pillar 4: Embrace and Adopt Information Communication Technology in all aspects of supply chain for HPT																							
	Outcome	***A robust information communication and technology system for HPT supply chain***																					
	Strategic Objectives *Strategic Objective 4.1: Regularly review strategies for ICT for HPT supply chain system to accommodate changes in technology* *Strategic Objective 4.2: Prioritize automation support for HPT supply chain at all levels* *Strategic Objective 4.3: Improve coordination and systems interoperability* *Strategic Objective 4.4: Adopt the GS1 Global Standards for track and trace in the supply chain for HPT*																						
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
4.1	**Strategic Objective 4.1: Regularly review strategies for ICT for HPT supply chain system to accommodate changes in technology**																							
4.1.1	Undertake regular review of strategies for ICT in HPT supply chain	HPT SC ICT Review Report	MOH, HIS																					4.2
4.1.2	Ensure that relevant data for decision making and performance monitoring is collected and reported on an established schedule	Reporting rate	MOH, HIS																					
4.1.3	Enhance the integration of LMIS taking into account existing IT infrastructure.	Integration of LMIS	MOH, HIS																					
4.1.4	Enhance the LMIS system to accommodate management of HPT redistribution, waste and reverse logistics	LMIS reporting rate	MOH, HIS																					
4.1.5	Improving LMIS capacity in terms of infrastructure, and human resource capacity	LMIS reporting rate	MOH, HIS																					
4.2	**Strategic Objective 4.2: Prioritize automation support for HPT supply chain at all levels**																							
4.2.1	Develop an HPT supply chain IT implementation plan with clearly defined service level standards	HPT SC ICT plan	MOH, CDOH																					
4.2.2	Define roles and responsibilities for HPT LMIS management across all levels	LMIS charter	MOH, CDOH																					
4.2.3	Develop protocols for HPT supply chain information	LMIS charter	MOH, CDOH																					
4.2.4	Dedicate adequate and competent human resources at national and county levels to support the implementation and long-term management of IT solutions	HPT ICT staff deployed	MOH, CDOH																					

Strategic Pillar 4: Embrace and Adopt Information Communication Technology in all aspects of supply chain for HPT																								
	Outcome	***A robust information communication and technology system for HPT supply chain***																						
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		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
4.2.5	Streamline reporting for HPT supply chain to minimize data collection tasks for health providers at facility levels	Reporting rate	MOH, CDOH																					
4.2.6	Undertake regular supportive supervision to improve data reliability and accuracy	Supervision report	MOH, CDOH																					91.3
4.2.7	Develop and implement a comprehensive plan of action for ensuring data visibility for users of the HPT supply chain	End to end visibility	MOH, CDOH																					
4.2.8	Establish HPT logistical coordination committees at county levels charged with the responsibilities of reviewing and analyzing data, addressing challenges and coordinating information sharing with stakeholders	Committee established	MOH, CDOH																					
4.2.9	Progressively automate facility level procedures, systems and tools for HPT management with a focus on reliable reporting, efficient ordering an inventory management	End to end visibility	MOH, CDOH, KEMSA																					
4.2.10	Develop and maintain a mechanism for gradually integrating private health facilities and academic institutions health facilities into the LMIS	LMIS integration	MOH, KHF																					1033.1
4.3	**Strategic Objective 4.3: Improve coordination and systems interoperability**																							
4.3.1	Improve data encryption for HPT HIS	Data encryption status report	MOH																					
4.3.2	Improve mechanisms relaying of HPT data to Kenya Health Information System (DHIS2)	Reporting rate	MOH																					0.0
4.3.3	Standardize reporting for all commodities through the national system	Reporting rate	MOH, DHPT																					0.0
4.3.4	Improve facility based data transmission from manual forms to electronic	Reporting rate	MOH, CDOH																					18.3

Strategic Pillar 4: Embrace and Adopt Information Communication Technology in all aspects of supply chain for HPT																							
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		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
4.3.5	Coordinate utilization of available HR capacity for maintenance of ICT systems at county level	Reporting rate	MOH, CDOH																					54.8
4.3.6	Improve budget allocations for supply chain related data reviews	Data review reports	MOH, CDOH																					36.5
4.3.7	Undertake quarterly county led data reviews and annual DQAs for HPT logistics data	DQA reports	CDOH																					0.1
4.3.8	Improve coordination of HPT HIS between programs, and divisions for HPT and HIS at MOH in system development and implementation	Joint Meeting Minutes	MOH HIS																					2.7
4.3.9	Finalize and roll out system integration framework for HPTs	Framework	MOH HIS																					0.0
4.4	**Strategic Objective 4.4: Adopt the GS1 Global Standards for track and trace in the supply chain for HPT**																							
4.4.1	Set up a technical working group for GS1 standards implementation	TWG meetings held	MOH HPT, MOH HIS																					
4.4.2	Identify and train champions for GS1 standards implementation	Champions trained	MOH HPT, MOH HIS																					2.7
4.4.3	Carry out a systems landscape assessment to determine opportunities to leverage on existing systems or integrate new technology	Landscape assessment report	MOH HPT, MOH HIS																					12.5
4.4.4	Develop a traceability approach and IT choreography model that accounts for the roles and capabilities of various trading partners	Approach developed	MOH HPT, MOH HIS																					2.7
4.4.5	Develop an implementation plan covering aspects of identification, location and data exchange	Implementation plan	MOH HPT, MOH HIS																					8.0

Strategic Pillar 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities																								
	Outcome	***A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products and technologies to the satisfaction of national needs and contributing to industrial development***																						
	Strategic Objectives *Strategic Objective 5.1: Define and provide incentives for Promoting local production of HPT* *Strategic Objective 5.2: Accelerate the full exploitation of Trade Related Intellectual Property Rights(TRIPS) Flexibilities*																							
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
5.1	**Strategic Objective 5.1: Define and provide incentives for Promoting local production of HPT**		MOH, MOITED, KHF																					
5.1.1	Revise and Implement the Stepwise GMP Roadmap Program		MOH, MOITED, KHF																					
5.1.1.1	*Revise/Update the Stepwise GMP Roadmap*	*GMP Roadmap revised*	MOH, MOITED, KHF																					2.4
5.1.1.2	*Establish a steering committee/ Technical working Group to guide and track implementation of the GMP Roadmap*	*TWG established*	MOH, MOITED, KHF																					
5.1.1.3	*Track implementation of the GMP Roadmap Actions*	*Annual Progress Report*	MOH, MOITED, KHF																					1.2
5.1.2	Develop a trackable mechanism for enhancing regulatory environment																							
5.1.2.1	*Review pre-licensing requirements, procedures with regard to site modification/new buildings guided by layout reviews*	*Prelicensing requirements reviewed*	PPB																					2.4
5.1.2.2	*Establish a risk categorization for companies on the basis of criticality of products, physical sites, and Quality Management Systems; and embed it into the audit procedures*	*Audit program based on risk categorisation*	MOH, PPB																					2.4
5.1.2.3	*Enforce and Report on compliance with risk based minimum licensing standards guided by the roadmap to compliance with WHO GMP standards*	*Compliance report*	MOH, PPB																					27.4
5.1.2.4	*Undertake annual risk based audits for compliance with minimum agreed licensing standards*	*Audit report*	MOH, PPB																					27.4
5.1.2.5	*Train and build a database of suitable service providers for Corrective Action and Preventive Action (CAPA) development*	*CAPA database*	MOH, KHF																					8.0

Strategic Pillar 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities																							
	Outcome	***A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products and technologies to the satisfaction of national needs and contributing to industrial development***																					
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		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
5.1.2.6	*Support pharmaceutical Manufacturers to perform gap analysis/CAPA facilitated by Pharmacy and Poisons Board*	*Gap Analysis Report*	MOH, PPB																					5.5
5.1.2.7	*Develop a HPT pricing policy that levels the playing field for local manufacturers doing business with government*	*Pricing Policy*	MOH, Treasury																					12.0
5.1.2.8	*Develop regulations to enforce use of generic names by prescribers and in all procurement by public health facilities*	*Regulations*	MOH																					2.4
5.1.2.9	*Review legislation (Pharmacy and Poisons Act, Cap 244) to support GMP enforcement*	*Reviewed legislation*	MOH																					4.8
5.1.2.10	*Establish a Bioequivalence Centre through PPP*	*Bioequivalence centre*	MOH, MOITED																					0.5
5.1.3	Design and implement an enhanced package of incentives to boost local manufacturing capacity for HPT																							
5.1.3.1	*Develop a structured incentive scheme for promoting compliance with WHO GMP*	*Incentives package developed*	MOH, Treasury																					2.4
5.1.3.2	*Roll out the incentive for compliance with WHO GMP*	*Incentives package rolled out*	MOH, MOITED, Treasury																					0.5
5.1.3.3	*Develop and implement a program for engagement of stakeholders on the GMP roadmap*	*Stakeholder engagement plan*	MOH, MOIED																					2.4
5.1.3.4	*Develop and implement a multi-stakeholder communication strategy for promoting local production and GMP Roadmap agenda*	*Communication strategy*	MOH																					2.4
5.1.3.5	*Mainstream the Buy Kenya Build Kenya(BKBK) strategy in HPT Supply Chain*	*BBK mainstreaming report*	MOIED																					0.5
5.1.4	Develop and implement a program for attracting foreign direct investment in local production of HPT																							0.0

Strategic Pillar 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities																								
	Outcome	***A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products and technologies to the satisfaction of national needs and contributing to industrial development***																						
	Strategic Objectives *Strategic Objective 5.1: Define and provide incentives for Promoting local production of HPT* *Strategic Objective 5.2: Accelerate the full exploitation of Trade Related Intellectual Property Rights(TRIPS) Flexibilities*																							
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
5.1.4.1	*Identify and map special economic zones suitable for pharmaceutical industry and mobilization*	*Mapping report*	MOH, MOITED, Treasury																					4.8
5.1.4.2	*Review market protection approaches for promoting local industry such as import controls and tariff barriers*	*Market protection report*	MOITED, Treasury																					2.4
5.1.4.3	*Develop and implement a strategy for affordable financing for local pharmaceutical industries*	*Financing strategy*	MOITED, Treasury																					4.8
5.1.5	Develop human resources for HPT supply chain through relevant education and training																							
5.1.5.1	*Conduct human resources needs assessment for scaling up local production (and implementing GMP Roadmap)*	*Needs assessment report*	MOH, MOTIED, MOE																					57.6
5.1.5.2	*Review curricula for HPT training to respond to industry needs (ensuring adequate capacity development for implementation of GMP Roadmap)*	*Reviewed curricula*	MOH, MOE																					7.2
5.1.5.3	*Identify and establish resource and training centers for GMP capacity development*	*Training centres*	MOH																					9.6
5.1.6	Develop and strengthen research and development platform		MOH, KEMRI																					
5.1.6.1	*Develop a platform for knowledge exchange and networking amongst pharmaceutical industrial players*	*Knowledge exchange platform*	MOH																					0.2
5.1.6.2	*Create R&D and Bioequivalence/CRO center to support local industries*	*Bioequivalence centre*	MOH																					120.0
5.1.6.3	*Develop an incentive program to promote investment in R&D in HPT*	*Incentive program*	MOH																					7.2
5.1.7	Formulate and implement incentives for development and production of active pharmaceutical ingredients through technology transfer																							

Strategic Pillar 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities																							
	Outcome	***A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products and technologies to the satisfaction of national needs and contributing to industrial development***																					
	Strategic Objectives *Strategic Objective 5.1: Define and provide incentives for Promoting local production of HPT* *Strategic Objective 5.2: Accelerate the full exploitation of Trade Related Intellectual Property Rights(TRIPS) Flexibilities*																						
		Milestone	**Responsibility**	**Timeframe**																			***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
5.1.7.1	*Develop targeted plan for technology transfer and investment that leverages on favorable government investment and industrial policies*	*Technology transfer plan*	MOIED																				4.8
5.1.7.2	*Undertake mapping to facilitate connections between investors, technology holders and potential recipients, utilizing trusted brokers*	*Mapping report*	MOIED																				2.4
5.1.7.3	*Develop a program for regulatory reliance and mutual recognition with other African Countries to create larger potential markets and remove hurdles to market access, building on existing economic cooperation efforts*	*Mutual recognition program progress report*	MOH, MOIED																				27.8
5.1.7.4	*Establish and provide funding for centers of excellence to house and amplify technical knowledge*	*Centres of excellence*	MOH, MOIED, Treasury																				80.0
5.1.7.5	*Develop a common database of API and raw material sources in collaboration with other African manufacturers*	*API database*	MOH, MOIED																				4.8
5.1.8	Consider government investment in local production strategic HPTs																						
5.1.8.1	*Develop strategy and framework for government investment in strategic HPT*	*Framework for government investment*	MOH, MOIED, Treasury																				4.8
5.1.8.2	*Undertake investment in local production guided by the developed framework*	*Report on implementation*	MOH, MOIED																				0.3
5.2	**Strategic Objective 5.2: Accelerate the full exploitation of Trade Related Intellectual Property Rights(TRIPS) Flexibilities**																						
5.2.1	Review and adopt the WTO Policy Tool for TRIPS Agreement Flexibilities																						

Strategic Pillar 5: Scale up Capacity for Research and Local Production of Health Products and Technologies and full exploitation of TRIPS flexibilities																								
	Outcome	***A vibrant local manufacturing industry (as demonstrated by increased share of domestic and regional market) for HPT producing quality health products and technologies to the satisfaction of national needs and contributing to industrial development***																						
	Strategic Objectives *Strategic Objective 5.1: Define and provide incentives for Promoting local production of HPT* *Strategic Objective 5.2: Accelerate the full exploitation of Trade Related Intellectual Property Rights(TRIPS) Flexibilities*																							
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
5.2.1.1	*Undertake a rapid review of readiness to apply the WTO policy tool for TRIPS agreement flexibilities for both manufacturing of drugs and exports*	*Assessement report*	MOH, MOITED																					2.4
5.2.1.2	*Operationalize the policy tool for TRIPS flexibilities*	*TRIPS tool adopted*	MOH, MOITED																					5.7
5.2.2	Strengthen Governance for TRIPS Agreement flexibilities implementation																							
5.2.2.1	*Establish an inter- agency committee to technical working group to track TRIPS implementation*	*Interagency committee in place*	MOH, MOITED, Treasury																					
5.2.2.2	*Produce quarterly report on the implementation of parallel importation rules for HPTs (and effect on affordability)*	*Quarterly report*	MOH, PPB																					3.6
5.2.2.3	*Produce status quarterly reports on TRIPS Agreement flexibilities invoked*	*Quarterly report*	MOH, KIPI																					3.6
5.2.3	Enhance Regional collaboration for implementation of compulsory licensing																							
5.2.3.1	*Identify and generate listing of products to be exploited under a pooling arrangement within the East African Region*	*List of products*	MOH																					3.8
5.2.3.2	*Support applications, based on the identified list, for compulsory licensing (and government use order) through regional pooling mechanisms*	*Report on applications supported*	MOH																					
5.2.4	Build local expertise in TRIPS Agreement flexibilities																							
5.2.4.1	*Build local expertise through technical assistance from WTO & WHO on implementation of TRIPS flexibilities*	*Technical Assistance requests*	MOH, MOIED																					7.6
5.2.4.2	*Implement capacity building plan with the support of Technical Assistance*	*Technical Assistance report*	MOH																					0.0

Strategic Pillar 6: Strengthen Human Resource Management and Development for HPT supply chain																								
	Outcome	***Adequate human resource for effective management of the health products and technologies***																						
	Strategic Objectives *Strategic Objective 6.1: Enhance recruitment, retention and rationalize deployment and distribution of human resource for HPT supply chain* *Strategic Objective 6.2: Review job descriptions for HPT staff to align to HPT functions* *Strategic Objective 6.3: Develop and implement a structured and sustainable capacity building program for HPT management*																							
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**	
6.1	**Strategic Objective 6.1: Enhance recruitment, retention and rationalize deployment and distribution of human resource for HPT supply chain**		MOH, DPHT																					
6.1.1	Undertake redistribution of HPT supply chain staff for improve equity	Staff deployment rationalised	MOH HRD; CPSB																					0.4
6.1.2	Undertake recruitment of HPT supply chain staff to fill in gaps, in consonance with the HRH Strategic Plan	Staff recruited	MOH HRD; CPSB																					4861.2
6.1.3	Strengthen the supervision and performance assessment of HPT supply chain professionals in the public sector		MOH, CDOH																					1.6
6.1.3.1	*Review supportive supervision checklist to cover all HPT Supply Chain aspects comprehensively*	*Reviewed checklist*	MOH, CDOH																					0.8
6.1.3.2	*Undertake joint quarterly supportive supervision for HPT Supply chain*	*Joint supervision undertaken*	MOH, CDOH																					
6.1.4	Advocate for career progression for HPT supply chain practitioners in the public health sector	Schemes of service	CDOH, MOH DPHT																					
6.1.4.1	*Undertake annual staff performance appraisals as per SPAS*	*Appraisals completed*	CDOH, MOH DPHT																					
6.1.4.2	*Process outstanding promotions for staff*		MOH, CPSBs																					
6.2	**Strategic Objective 6.2: Review job descriptions for HPT staff to align to HPT functions**		MOH, CDOH, CPSB, PSC																					
6.2.1	Review Schemes of Service for pharmacists, pharmaceutical technologists, nutritionists, medical laboratory technologists, dentists, COH and dental technologists, radiology, and supply chain management officers to address HPT supply chain issues holistically and align to practice	Reviewed Schemes	MOH, CDOH, CPSB, PSC																					11.4
6.2.2	Adopt and disseminate the revised schemes of service	Adopted Schemes of service	MOH HRD, CPSB																					7.8

Strategic Pillar 6: Strengthen Human Resource Management and Development for HPT supply chain																								
	Outcome	***Adequate human resource for effective management of the health products and technologies***																						
	Strategic Objectives *Strategic Objective 6.1: Enhance recruitment, retention and rationalize deployment and distribution of human resource for HPT supply chain* *Strategic Objective 6.2: Review job descriptions for HPT staff to align to HPT functions* *Strategic Objective 6.3: Develop and implement a structured and sustainable capacity building program for HPT management*																							
		Milestone	**Responsibility**	**Timeframe**																				***Estimated Cost (KES M)***
				Year 1				**Year 2**				**Year 3**				**Year 4**				**Year 5**				
				Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
6.3	**Strategic Objective 6.3: Develop and implement a structured and sustainable capacity building program for HPT management**		MOH, KHPOA																					
6.3.1	Develop and roll out of institution based CPD programs on HPT supply chain	CPD programs developed and rolled out	MOH, KHPOA																					32.4
6.3.2	Formulate and roll out guidelines for On the Job Training (OJT) in HPT supply chain functions	OJT rolled out	MOH, KHPOA																					0.4
6.3.3	Enhance capacity of the division of HPT, MOH to coordinate capacity building on HPT supply chain	HPT function at MOH strengthened	MOH, HRD																					
6.3.4	Strengthen capacity building for health workers in appropriate use of HPTs through Good Prescribing Practices (GPP) ,Good Dispensing Practices (GDP) by making use of pre- & post-service training, guidelines and targeted supportive supervision	Capacity building program rolled out	MOH																					26.2
6.3.5	Institute systematic training of users of medical equipment devices at time of commissioning/ installation and thereafter as required.	Training undertaken	MOH, Medical Engineering																					0.8
6.3.6	Establish and maintain an updated electronic HPT supply chain capacity building database	Database established	MOH, DPHT																					
6.3.7	Review and harmonise in-service training for HPT supply chain	In-service training reviewed	MOH, KHPOA																					8.0
6.3.8	Review pre service curriculum for health workers to ensure that courses covering principles of managing HPTs, procurement, selection, distribution, quality, information management systems assurance and use are fully integrated	Pre-service training curricula reviewed	MOH, MOE																					4.3

ANNEX II – MONITORING AND EVALUATION MATRIX

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
1.1	Proportion of Functional Medicines Therapeutic Committees at hospital level	% of facilities facilities with functional MTC out of all the facilities that have established MTC	KHIS/HFA	Quarterly	MOH, CDOH	TBD	80	100	100	100	100	Functionality criteria for MTC to be reviewed & disseminated
1.2	Proportion of functional MTCs at County Level	% of counties with functional MTCs. Functionlity based on criteria comprising official members, approved TOR, monthly meetings with documentation, action plan, updated eHPT lists and policies, undertaking HPT use problem studies/surveys, reports, takes action on the basis of findings	Surveys, MTR	Annually	MOH, CDOH	2.12 (1 county)	50	100	100	100	100	
1.3	Number of HPT Supply Chain Regulations Formulated	Number of targetted HPT regulations formulated and approved	Hansard	Annually	MOH	TBD		1	1	1		Generics, PV, PMS
1.4	Proportion of HPT sampled by NQCL failing quality tests	Proportion of samples tested by NQCL, out of the total samples tested, that fail the QC tests	NQCL Reports	Quarterly	MOH, NQCL	TBD	0.05%	0.05%	0.05%	0.05%	0.05%	Target is < 0.05%
1.5	Proportion of health products and technologies sampled from post market surveillance that fail quality tests	% of samples from PMS failing QC tests for comliance with recognised pharmacopoiea, out of the samples collected during PMS	PMS Surveys, PPB Quarterly Reports	Annually	MOH, PPB	TBD	0.05%	0.05%	0.05%	0.05%	0.05%	Target is < 0.05%
1.6	Proportion of hospitals with functional drug information service	% of hospitals with functional drug information service in the reporting period, out of all hospitals that have established drug information service. An established information service has dedicated room, dedicated staff, adequate reference material and equipment, SOPs, completed query response forms,medicines education program and reports	Survey and Support Supervision	Semi-annually	MOH, CDOH	TBD	100	100	100	100	100	
1.7	Proportion of health facilities with updated Standard Treatment Guidelines (STG)	% of health facilities that have the latest approved edition of STG (for the appropriate level)	KHIS	Annually	MOH, CDOH	TBD		100	100	100	100	
1.8	Proportion of prescriptions for different conditions complying with approved standard treatment guidelines and protocols	% of prescriptions for different conditions complying with approved standard treatment guidelines and protocols	Survey and Support Supervision	Annually	MOH, CDOH	TBD	100	100	100	100	100	
1.9	Proportion of Antibiotics under Reserve classification prescribed in level 4 or lower levels[#]	% of Antibiotics under Reserve classification prescribed in level 4 or lower levels	Routine Reports, Surveys	Annually	MOH, CDOH	NA	0	0	0	0	0	
1.11	Proportion of medicines prescibed from the facility's medicines list	% of medicines prescibed from those listed on the medicines list of the health facility, developed by the Medicines and Therapeutics Committee	Survey and Support Supervision	Quarterly	MOH, CDOH	TBD	100	100	100	100	100	
1.12	Proportion of medicines prescribed by generic name	% of medicines prescibed by generic name	Survey	Quarterly	MOH, DHPT	TBD	100%	100%	100%	100%	100%	

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
1.13	Average number of medicines dispensed per prescription	The total number of of medicines prescribed at OPD divided by the number of enounters, as a measure of degree of polypharmacy	Survey and Support Supervision	Quarterly	MOH, CDOH	TBD	2	2	2	2	2	Target is <2
1.14	Proportion of medicines prescribed from the essential list	% of medicines prescibed from those listed in the KEML	Survey	Quarterly	MOH, DHPT	TBD	100%	100%	100%	100%	100%	
1.15	Proportion of encounters with one or more antibiotic prescribed	The % of encounters with one or more antibiotic prescibed at the facility out patient departments (based on the total number of encounters)	Survey and Support Supervision	Annually	MOH, CDOH	TBD	20%	20%	20%	20%	20%	
1.16	Number of locally produced Traditional and alternative medicines (TAM) registered	Number of locally produced Traditional and alternative medicines (TAM) as per PPB register	PPB	Quarterly	MOH, DTAM	TBD						
1.17	Proportion of clients with fully filled prescriptions	The % of clients who receive all the prescribed medicines (100%) from health centre and dispensary, out of all the clients who received prescriptions in a given period of time	KHIS	Monthly	MOH, CDOH	TBD	100	100	100	100	100	
1.18	Number of counties sensitized on essential medicines list	Number of counties sensitized on essential lists for HPT (KEML, KEDL, KEMSL)	MOH DHPT Reports	Annually	MOH, DHPT	NA	47	47	47	47	47	
1.19	Proportion of sampled HPTs that are adequately labelled	% of medicine packages that are labelled with adequate information to aid rational use by patients. Adequate lable includes the patient name, name of medicine, dose, frequency, duration of use, quantity dispensed, and route of administration.	Survey and Support Supervision	Quarterly	MOH, CDOH	TBD	100	100	100	100	100	
1.21	Proportion of counties with functional commodity security TWGs	% of counties that have functional HPT supply chain TWG (commodity security TWG) as per defiend criteria	MOH DHPT Reports	Annually	MOH, CDOH	80%	100	100	100	100	100	
1.22	Number of laws enacted or ammended	Number of targetted HPT laws formulated and assented to	Hansard	Annually	MOH	TBD	1	1	1			FDA, Review of KEMSA Act, TAMs Act
2.01	Quantification (and forecast) accuracy for tracer products	Percentage difference between forecasts previously made for specified period of time and he acutal consumption of issues data for that period	Facility Forecast Data	Annually	MOH, DHPT	TBD	75%	75%	80%	80%	85%	
2.02	Percentage of Health facilities with stock out of tracer non-pharm for 7 consecutive days in a month	% of facilities reporting more than 7 days in a month of number of days in which tracer items was not available in a specified period of time	Survey and Support Supervision	Quarterly	MOH, CDOH	44%	20	10	0%	0%	0%	

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
2.03	Average wastage rate of health products	% of the stock of products, in value, that are not usable due to expiration or damage during a period, out of the total value of the products received(adjusted for opening balances) during the same period	KHIS	Quarterly	MOH, CDOH	TBD	3%	3%	3%	3%	3%	>3%
2.04	Proportion of health facilities disposing HPT waste in time	Proportion of health facilities that have disposed HPT that is not fit for use at least once in the past 12 months (out of all the health facilities that have HPT waste). Waste includes expired, damaged and HPT with quality issues.	Routine Reports, Surveys	Annually	MOH, CDOH	TBD	100	100	100	100	100	
2.05	Average inventory accuracy rate	Proportion of agreement between stock record balances and physical stock counts for stock items reviewed for accuracy	Routine Reports, Surveys	Quarterly	MOH, CDOH	TBD	80%	80%	80%	80%	80%	
2.06	Average availability of essential medicines in health facilities	% of the tracer medicines available throughout the months (averaged over all tracer drugs under the review in the month)	LMIS, KHFA	uarterly/Annua	MOH, DHPT	44	80	90	100	100	100	
2.07	Proportion of hospitals with Parenteral feeds (Level 4,5,6 facilities)	% of hospitals (Level 4,5,6 facilities) with Parenteral feeds, out of all the hospitals in the master facility list	HIS (Clinical Nutrition/ Dietetics -MOH 711)	Quarterly	MOH, CDOH	-	50	65	80	100	100	
2.08	Average availability of basic diagnostic tracer items in facilities	% of the tracer diagnostic items available throughout the months (averaged over all tracer diagnostic items under the review in the month)	LMIS, KHFA	uarterly/Annua	MOH, DHPT	56	85	95	100	100	100	
2.09	Percentage of primary health facilities with a package of basic equipment by level of care	% of health facilities that have the essential package of basic medical equipment that is functional, as evidenced by the facility's medical equipment inventory list	KHHFA /SDI	Survey	MOH	20	40	45	50	60	70	
2.12	Percentage of sampled Health facilities with stock out of the tracer medicines for 7 consecutive days in a month	% of facilities reporting more than 7 days in a month of number of days in which tracer drugs was not available in a specified period of time	Survey and Support Supervision	Quarterly	MOH, CDOH	44%	20	10	0%	0%	0%	
2.13	Proportion of annual requirement of safe blood available for transfusion	% of annual requirements for safe blood that is available for transfusion	KNBTS Reports	Quarterly	MOH, KNBTS	TBD	50	60	70	80	90	
2.14	Order fill rate of tracer medicines by quantity per item as (%)	% of items ordered by health facilities from KEMSA(or other private supplier) over a period of time that are filled correctly at least 80% in terms of quantities requested of those items	KHIS/LMIS	Quarterly	MOH, DHPT; KEMSA	85	95	95	100	100	100	List of tracer items included to be disseminated

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
2.15	Order fill rate of tracer non-pharmaceutical commodities by quantity per item as (%)	% of items ordered by health facilities from KEMSA(or other private supplier) over a period of time that are filled correctly at least 80% in terms of quantities requested of those items	KHIS/LMIS	Quarterly	MOH, DHPT; KEMSA	85	95	95	100	100	100	List of tracer items included to be disseminated
2.16	Percentage of Hospitals with any of the tracer basic lab diagnostic out of stock for 7 consecutive days in a month (HIV Diagnostic capacity, Malaria diagnostic capacity, Syphilis rapid test, Urine test for pregnancy, Blood glucose, Urine dipstick-glucose, Urine dipstick-protein, Haemoglobin)	% of facilities reporting more than 7 days in a month of number of days in which tracer items was not available in a specified period of time	KHFA	Quarterly	MOH, DHPT	-	37	10%	0%	0%	0%	
2.17	Proportion of hospitals with parenteral feeds (Level 4,5,6 facilities)	% of hospitals with required stock levels of parenteral feeds	KHIS	Monthly	MOH, CDOH	TBD	50	65	80	100	100	
2.18	Average lead time from ordering to delivery at health facility	Average number of days it takes by supplier to deliver products once orders are submitted to the supplier	Routine Reports, Surveys	Biannually	MOH, CDOH	TBD	10	10	10	10	10	
2.19	Proportion of facilities that maintain acceptable storage conditions	% of health facilities that meet the minimum acceptable storage conditions	Routine Reports, Surveys	Annually	MOH, CDOH	TBD	100	100	100	100	100	The good storage standards will be defined and disseminated
3.01	Number of HPT Review Meetings Undertaken at national and county level	Number of HPT Supply Chain and HPT Review Meetings conducted within as per required administrative level (MOH (HPT ICC, County, SubCounty)	Reports of Review Meetings (CDOH, MOH)	Annually	MOH, CDOH	TBD	4	4	4	4	4	
3.02	Number of functional HPT supply chain partnerships established	Number of formal partnerships, based on MOU signed, under implementation	MOH Report	Annually	MOH	TBD						
3.03	Number of public private HPT supply chain partnerships established	Number of formal partnerships, based on MOU signed, under implementation	MOH Report	Annually	MOH	TBD						
3.04	Proportion of donor to government funding for essential HPT	% of total annual expenditure on HPTs funded from external sources	MOH NHA	Annually	MOH	TBD	20%	20%	20%	15%	15%	
3.05	Per capita public spending on HPT	Annualallocation (national and county governments) to HPT divided by the national population	MOH Reports, and NHA	Annually	MOH, CDOH	TBD						
3.06	Proportion of international indicator price paid by bulk purchasers (KEMSA, MEDS) for essential HPT	Proportion of prices paid by MEDS (and KEMSA) for a defined basket of eHPTas a proportion of international indicator price for a defined basket of essential HPT	MOH, KEMSA, MEDS Reports	Annually	MOH DHPT	TBD						

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
3.07	% contribution of government for public health commodities in public health programs (HIV, TB, Malaria, Nutrition, Vaccines & FP products)	% contribution of government in co-financing for public health commodities in public health programs (HIV, TB, Malaria, Nutrition, Vaccines & FP products)	MOH Financial Reports, NHA	Annually	MOH	<2%	6	8	10	15%	15%	
3.08	Number of joint (National and County) supply chain audits conducted	Number of HPT supply chain audits undertaken jointly by national, county governments and partners	MOH Audit Reports	Quarterly	MOH, CDOH	N/A	4	4	4	4	4	
4.01	Proportion of institutions (including health facilities) submitting timely and complete HPT reports	% of health facilities, out of al health facilities expected to report, that submit timely and complete reports	KHIS	Quarterly	MOH, CDOH	TBD	100	100	100	100	100	
4.02	Proportion of facilities reporting electronically on HPT supply chain	% of health facilities, out of al health facilities expected to report, that submit electronic reports	KHIS	Monthly	MOH, CDOH	TBD	100	100	100	100	100	
4.03	Availability of end-to-end visibility of tracer HPTs through automation	Real time end to end data on tracer items available under one system	LMIS, KHIS	Annually	KEMSA, MOH, Counties	0	100	100	100	100	100	
5.01	Proportion of domestic market held serviced by local pharmaceutical and medical supplies	% of HPT public procurement by value, out of the total public spending on HPT, that is serviced by local manufacturing firms	MOH, KEMSA Reports	Annually	MOH, CDOH	22%	30%	40%	45%	47.5%	50%	
5.02	Utilization of existing capacity of local pharmaceutical and medical supplies manufacturers	% of local manufacturers production/factory capacity that is utilised	Survey, FKPM Reports	Annually	FKPM, MOH	TBD	45%	50%	55%	60	70%	
5.03	Number of local manufacturers fully compliant with WHO GMP standards	Number of local manufacturers(local manufacturing plants) assessed as fully compliant with WHO GMP Standards	Survey, PPB Reports	Annually	MOH, PPB	TBD	5	5	5	7	7	
5.04	Number of TRIPS Agreement Flexibilities invoked (TBD)	Number of TRIPS Agreement flexibilities invoked	Reports from MOH, PPB and KIPI	Annually	MOH, KIPI	TBD	2	2	2	2	2	
5.05	Number of API manufacturers	Number of local firms producing APIs	MOH, PPB	Annually	MOH, PPB	TBD	2	2	3	3	3	
5.06	Number of WHO prequalified products produced locally	Number of new products, that are WHO prequalified, produced by local firms	MOH, PPB	Annually	MOH, PPB	TBD	5	5	10	15	20	
5.07	Joint Ventures with WHO GMP Compliant manufacturers	Number of new joint ventures established with firms that have WHO cGMP	MOH, PPB	Annually	MOH, PPB	TBD	2	2	2	2	2	
5.08	Exports of locally produced HPTs by WHO GMP compliant producers in KES B	Value of exports of HPTs by local manufacturers who have external certification for GMP	Annual Economic Survey Report, KNBS	Annually	MOH, PPB	TBD	15	20	25	28	30	
5.09	Number of essential HPTs whose demand can be met in full through local production	Number of essential HPTs whose demand can be met in full through local production	MOH, MOITED Reports	Annually	MOH, MOITED	TBD					8	

							Targets (Annual)					
Ref	**Indicator**	**Indicator Definition**	**Data Source**	**Frequency**	**Responsibility**	**Baseline (Yr in brackets)**	**20/21**	**21/22**	**22/23**	**23/24**	**24/25**	**Remarks**
6.01	Proportion of academic institutions training HPT supply chain professionals with HPT supply chain module integrated in their curricula	The % of academic institutions training HPT supply chain professionals at degree and diploma level with HPT supply chain core concepts integrated in their curricula	MOH and MOE Reports	Annually	MOH, DHPT	TBD	50%	100%	100%	100%	100%	
6.02	Proportion of HPT supply chain positions established and filled in the public health sector	The % of HPT Supply Chain health workforce positions that are established at health facilities and coordination units that are filled	MOH, Human Resource Reports	Annually	MOH, CDOH	TBD	75%	80	80	80	80	
6.03	Proportion of health facilities that receiving supportive supervision on HPT	% of health facility facilities that receive supportive supervision on their HPT supply chain activities by immediate administrative units (MOH, CHMT, SCHMT) applying a standardised checklist within a specified time period.	Routine Reports, Surveys	Annually	MOH, CDOH	TBD	100	100	100	100	100	


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