



MINISTRY OF HEALTH



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TRADE & INDUSTRY

KENYA HEALTH PRODUCTS AND TECHNOLOGIES LOCAL MANUFACTURING STRATEGY

2026 – 2030

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KENYA HEALTH PRODUCTS AND TECHNOLOGIES LOCAL MANUFACTURING STRATEGY 2026 – 2030

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STATEMENT BY THE CABINET SECRETARIES

The Government of Kenya is guided by the 2010 Constitution, the Vision 2030 and the Bottom-Up Economic Transformation Agenda in striving to transform the country for global competitiveness and prosperity with a high quality of life by 2030.

His Excellency the President of the Republic of Kenya is the African Union Champion for Local Manufacturing. His proclamation to grow the proportion of our consumption of health products produced locally provides impetus for the development of this strategy.

The Government is cognizant of the immense benefits of local manufacturing of health products and technologies, and this strategy presents a timely opportunity to:

1. Galvanize all the relevant Government Ministries, Departments, Agencies, and other stakeholders to enhance local HPT manufacturing as a key pillar for health security, sovereignty, industrialization, self-reliance, and socio-economic transformation. This will entail review and amendment of some existing laws and/or creation of new enabling ones.
2. Align all development and implementation partners, financial institutions, and private sector leaders around priority investment and policy actions to promote local manufacturing.
3. Expand both the domestic and foreign markets for our local manufacturers by, not only promoting the Buy Kenya-Build Kenya agenda, but also taking advantage of existing bilateral, regional, continental and global frameworks.

We look forward to full implementation of the Kenya Health Products and Technologies Local Manufacturing Strategy (2026 – 2030) towards socio-economic empowerment of our people and a healthy Nation.



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Hon. Lee Kinyanjui, EGH
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 Ministry of Investment, Trade and Industry

FOREWORD

The Government is committed to delivering quality healthcare to all Kenyans in line with the Constitution of Kenya 2010. Through Kenya Health Policy 2014-2030, the Ministry of Health (MOH) strives to ensure that effective, safe, and affordable health products and technologies (HPT) are always available and rationally used, while moving towards maintaining a strategic national reserve. However, Kenya still relies heavily on imports to meet its HPT needs, which poses healthcare risk if global supply chains are disrupted. Local production of essential Health Products and Technologies, research and innovations are pivotal in reducing this dependency on imports.

In support of local manufacturing, The President pronounced in October 2023 that, by 2026, at least 50% of essential health products should be manufactured locally. The Government is committed to creating an enabling environment for local manufacturing sector for HPTs through various approaches like the establishment of Special Economic Zones (SEZ), favourable regulations and incentives, development of the Preferential Procurement Master Roll which comprises products (including 347 Health Products and Technologies) to be accorded preferential procurement in public sector, among others.

Demand for locally produced goods and services by the public and private sectors must be encouraged. Inculcating among Kenyan citizens a preference and a sense of patriotism for Kenyan goods and services as a means of supporting the local industry, and consequently the economy, is a key objective of the Government through the “Buy Kenya-Build Kenya” strategy by the Ministry of Investment, Trade and Industry.

It is our belief that this document will provide strategic direction and impetus to spur desired growth of Kenya’s local Health Products and Technologies manufacturing industry. This will in turn actualize local production quality and affordable life-saving products to support the Government to deliver on healthcare commitments espoused in the Universal Health Coverage.



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PREFACE

The Kenya Local HPT Manufacturing Strategy (2026-2030) is a culmination of efforts by the Government of Kenya, to develop a blueprint towards progressive growth of Kenya's local Health Products and Technologies manufacturing into a robust, efficient and sustainable industry. The vision is to meet our growing local Health Products and Technologies demand as well as expand into regional markets.

The development of this Strategy would not have been possible without the dedication of diverse stakeholders who provided invaluable contributions and insights. It outlines the health system in Kenya, the current situation regarding the economics of local HPT manufacturing industry and its maturity-level, and policies and regulations that impact the industry, while drawing on lessons from other countries in Africa and beyond.

This document incorporates detailed SWOT, PESTEL and Pharmaceutical Value Chain (PVC) analyses, all of which provided a good basis for the synthesis of strategic issues, imperatives, priorities, and outcomes-based interventions or results areas. The strategic pillars (priorities) and goals of this Strategy are threefold:

Pillar 1: Accelerating priority regulatory and policy reforms for the industry;

- **Goal 1: Aligning governance design and operating architecture for the industry**

Pillar 2: Scaling-up and diversification of Local HPT Manufacturing capacity

- **Goal 2: Increasing utilization of local manufacturing capacity by 70%**

Pillar 3: Demand generation and market assurance

- **Goal 3: Market development through access, coordination and management**

To achieve these priorities and goals, the Strategy outlines various outcome-based interventions, a costed implementation and coordination plan, a resource mobilization plan, a monitoring, evaluation, and reporting framework, a risk management framework and a proposed governing structure to align local with regional agenda to ride on the political goodwill of the President as the AU champion on local manufacturing in Africa.

This Strategy will be an important resource for the public and private sectors, policy and decision makers; managers at various levels; development and implementing partners, and industry players including local manufacturers. It is our conviction that it will serve as a reference and guide to strengthen our local Health Products and Technologies manufacturing industry.



A handwritten signature in blue ink, appearing to read 'Patrick Amoth', written over a light blue background.

Dr. Patrick Amoth, CBS

DIRECTOR GENERAL FOR HEALTH

ACKNOWLEDGEMENT

The Ministry of Health acknowledges the support made by various stakeholders towards the development of this Strategy. In particular, we wish to acknowledge the commitment and contribution of the Directorate of Health Products and Technologies, the Division of Quality Assurance and Market Shaping for the leadership and stewardship during the Strategy's development process; other officers in the Ministry of Health who provided technical and professional inputs; other Ministries Departments and Agencies (MDAs); Non-Government Organizations (NGOs), Faith-Based Organizations (FBOs), training institutions, regulatory bodies, professional associations, local manufacturers and distributors for their inputs and insights which enriched the content of this Strategy.

We appreciate the secretariat and the consultants Justus Ogando and Joseph Kimani, who all worked together in steering the development process and ensuring the content of this document is comprehensive, accurate, relevant and in line with the desired standards.

We greatly appreciate the financial and technical support from Africa Resource Centre, Clinton Health Access Initiative, PATH Kenya, CIPS-HPA, AMREF/CHReaD, PS Kenya, World Health Organisation - Kenya Country office and Village Reach in the development process of this Strategy.

Finally, we thank all who participated and supported in various ways, and provided their expertise in reviewing, editing, formatting and designing of this Strategy.



Dr. Nazila Ganatra,
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ACRONYMS AND ABBREVIATIONS

AfCFTA	African Continental Free Trade Area
AfDB	African Development Bank
AMA	African Medicines Agency
API	Active Pharmaceutical Ingredients
AU	African Union
BETA	Bottom-Up Economic Transformation Agenda
Africa CDC	Africa Centres for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
COMESA	Common Market for Eastern and Southern Africa
DHPT	Directorate of Health Products and Technologies
EAC	East Africa Community
EPRA	Energy and Petroleum Regulatory Authority
EPZ	Export Promotion Zone
FEAPM	Federation of African Pharmaceutical Manufacturers
FIF	Facilities Improvement Financing
FKPM	Federation of Kenya Pharmaceutical Manufacturers
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
GMP	Good Manufacturing Practice
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HPT	Health Products and Technologies
IAEA	International Atomic Energy Agency
IFC	International Finance Corporation
IGAD	Intergovernmental Authority on Development
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KAP	Knowledge, Attitude and Practices
KAPI	Kenya Association of Pharmaceutical Industry
KDHS	Kenya Demographic and Health Survey
KEBS	Kenya Bureau of Standards
KEML	Kenya Essential Medicines List
KEMLC	Kenya Essential Medical Laboratory Commodities
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KEMSL	Kenya Essential Medical Supplies List
KEPROBA	Kenya Export Promotion and Branding Agency
KEVEVAPI	Kenya Veterinary Vaccines Production Institute
KHIS	Kenya Health Integrated System
KHPTRA	Kenya Health Products and Technologies Regulatory Authority
KIPI	Kenya Industrial Property Institute
KMHFL	Kenya Master Health Facilities List
KNBS	Kenya National Bureau of Statistics
KNPP	Kenya National Pharmaceutical Policy

KPA	Kenya Pharmaceutical Association
KRA	Kenya Revenue Authority
KU	Kenyatta University
KUTRRH	Kenyatta University Teaching, Research and Referral Hospital
LM	Local Manufacturing
LVAC	Local Value-Added Content
MEDS	Mission for Essential Drugs and Supplies
MITI	Ministry of Industry Trade and Investments
mRNA	Messenger Ribonucleic acid
NACOSTI	National Commission For Science, Technology and Innovation
NRTH	National Referral and Teaching Hospital
NEMA	National Environmental Management Authority
NGO	Non-governmental Organization
NMRA	National Medicines Regulatory Authority
NQCL	National Quality Control Laboratory
PESTEL	Political, Economic, Social, Technological, Environmental and Legal factors
PLI	Performance-Linked Incentives
PMPA	Pharmaceutical Manufacturing Plan for Africa
PPB	Pharmacy and Poisons Board
PPAD	Public Procurement and Assets Disposal
PPP	Public Private Partnership
PPV	Pulse Pressure Variation
PSK	Pharmaceutical Society of Kenya
PVC	Pharmaceutical Value Chain
R&D	Research and Development
SEZ	Special Economic Zone
SHA	Social Health Authority
SHIF	Social Health Insurance Fund
SME	Small and Medium Enterprise
SWOT	Strengths, Weaknesses, Opportunities and Threats
TAM	Traditional and Alternative Medicines
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UHC	Universal Health Coverage
UoE	University of Eldoret
UoN	University of Nairobi
USIU	United States International University
VAT	Value Added Tax
WHO	World Health Organization

EXECUTIVE SUMMARY

This Local Manufacturing Strategy is structured to position Kenya’s healthcare as an investment for social impact, equity, economic growth, commercial traction, and sustainability. As a catalyst for self-reliance and health security, the strategy advances Kenya’s strategic interests regionally, riding on the goodwill of the President’s lead role as AU champion on Local Manufacturing.

Key insights from the landscape analysis indicate a fragmented local manufacturing ecosystem with cross-cutting challenges that span multiple ministries and agencies, limiting progress toward Universal Health Coverage. The sector remains siloed across supply chain, research, regulation, trade, product development, financing, human capital, and health data systems, resulting in persistent vulnerability to import and donor dependency, geopolitical disruptions, and climate-related health threats.

Key imperatives include strengthening private sector-led Pharmaceutical Value Chain Level 3 manufacturing (final dosage/fill-finish), where a few manufacturers account for most local production, through enhanced government–private sector collaboration to align commercial sustainability with national socio-economic goals. The strategy also emphasizes commercialization of locally manufactured vaccines through Kenya Biovax, contingent on PPB achieving ML-3 status. Additional priorities include developing underexploited Pharmaceutical Value Chain Level 4 (API production) and Level 5 (R&D), which require advanced technology, specialized skills, and significant investment despite available government incentives. This further highlights the need for regional API supply-chain collaboration across Africa and calls for a dedicated strategy to strengthen the largely under-prioritized diagnostics and medical devices sector.

Pivoting on three (3) strategic pillars *i.e. Scale-up and diversification of local capacity utilization; Accelerating priority regulatory reforms; Demand generation and market assurance*, this strategy advances structured focus and direction to move from intent-to-execution and avoid persistent abstract narratives on vulnerability and LM potential to actually delivering on the long overdue promise of local HPT manufacturing for self-reliance, health security and economic growth.

This strategy positions Kenya as a hub and centre of excellence for shaping the future of regional supply chain and advanced manufacturing, through partner-led regional accelerator programs that can seed investments needed to scale-up technical capabilities and industrial skills, align regulatory policies, public-private-partnership for technology transfer, and market coordination. It also aims to demystify negative perspectives on LM industry’s unattractiveness for sustainable finance, by prioritizing and navigating complex regulatory environment, technology partnership, and building replicable operational models that meet international compliance standards. This will de-risk the LM investment landscape and attract capital needed for infrastructure upgrades and foster private sector-led growth for supply stability, health security, and a future of shared prosperity for Kenya and Africa.

1 Introduction

1. Introduction

1.1 Strategic Planning Methodology

The following framework guided the situation analysis, identification of institutional and industry risks, defining of imperatives, development of strategies, M&E, implementation and resource plans.

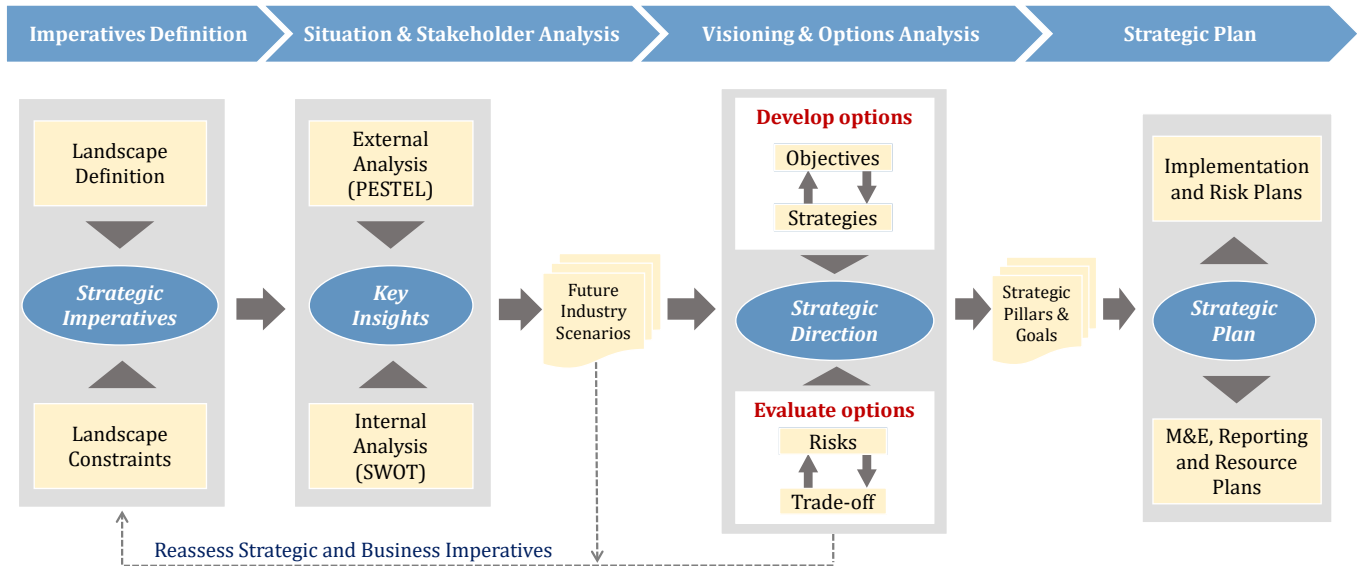


Figure 1: Framework for Strategic planning methodology

1.2 Health Sector Landscape

The health and HPT market is highly regulated through various policy, legal, and regulatory frameworks to ensure quality, affordability, reliability, and accessibility of essential care services and products, and guarantee health as a basic human right as enshrined in the Constitution of Kenya (2010).

Kenya’s health sector and HPTs’ market has significantly transformed over recent years, partly driven by a rapid evolution and development of robust legal frameworks and instruments such as the 2010 Constitution, Vision 2030 Economic Development Plan, the Kenya Health Policy (2014 – 2030), and various Medium-Term Plans (MTPs) and Medium-Term Expenditure Frameworks (MTEFs).

These concerted efforts galvanized the establishment of Universal Health Coverage (UHC) as one of the highest priorities of the government. UHC is driving significant change for both the public and private health sectors, supported by the following legislations to anchor its implementation, which by extension impact the HPT landscape: -

- Social Health Insurance Act 2023
- Digital Health Act (DHA) 2023
- Primary Health Care (PHC) Act.
- Facility Improvement Financing (FIF) Act 2023

As economic growth continues to increase demand for better quality and affordable health services, current regulatory policy frameworks have only marginally improved health resource mobilization. Following recent geopolitical shifts in global funding landscape, Kenya’s health system has been adapting in ways unanticipated before, with increased focus on optimizing impact from the limited domestic resource allocated to health sector in the face of declining donor resources.

As the government continued to navigate the growing public debt and reduced resources to sustain essential care services, priorities are being reassessed with new service delivery approaches tested out of necessity to support Health Programs through the restructuring phase.

a) Health Systems in Kenya

The health sector’s significant transformation in recent years is driven by robust legal and regulatory frameworks and rapid technological advancements as per the **State of Kenya Health Market – 2024 Assessment Report**. While the country has made remarkable progress across many health statistics, there still remain areas of improvement. Table 1 shows some of Kenya’s key health statistics.

Table 1: Key Health Statistics in Kenya

Indicator	Baseline	Source	Year
Population (million)	53.3	Analytical Report on Population Projections - KNBS	2022
Population growth rate	2%	WHO data (Kenya)	2023
Median Age (Years)	21.2	CIA.gov	2024
Life Expectancy at birth (Years)	66.8	KDHS	2022
TB incidence rate per 100,000 population	237	WHO estimates/KHIS tracker	2022
Number of AIDS related deaths	18,473	KENPHIA/Annual HIV estimates	2022
Probability of premature mortality from NCDs (%)	21%	WHO NCD Progress Monitor	2022
Malaria incidence (Total malaria cases per 1000 population at risk)	105.2	KHIS	2022
Maternal mortality ratio (per 100,000 live births)	355	Population Census	2019
Under-five mortality rate (per 1000 live births)	41.1	KDHS	2022
Neonatal mortality rate (per 1000 live births)	21	KDHS	2022

Kenya’s health system is devolved into a national and county tiers based on the Constitution 2010, with the aims of attaining the highest standards of quality healthcare for the entire population through various structures and levels of the health system.

Kenya’s health sector goal, articulated in the Health Policy (2014-2030), provides direction towards attainment of the highest possible standards of quality health in a manner responsive to the needs of the population. Adequate, quality and affordable Health Products and Technologies (HPTs) are integral to realizing the aspirations of the Kenya Health Policy. The Kenya Health Policy Orientations, Objectives, and Goals demonstrate that HPT is integral for the achievement of Kenya’s Health Policy goal of “attaining the highest possible standard of health in a responsive manner”. (Figure 2)

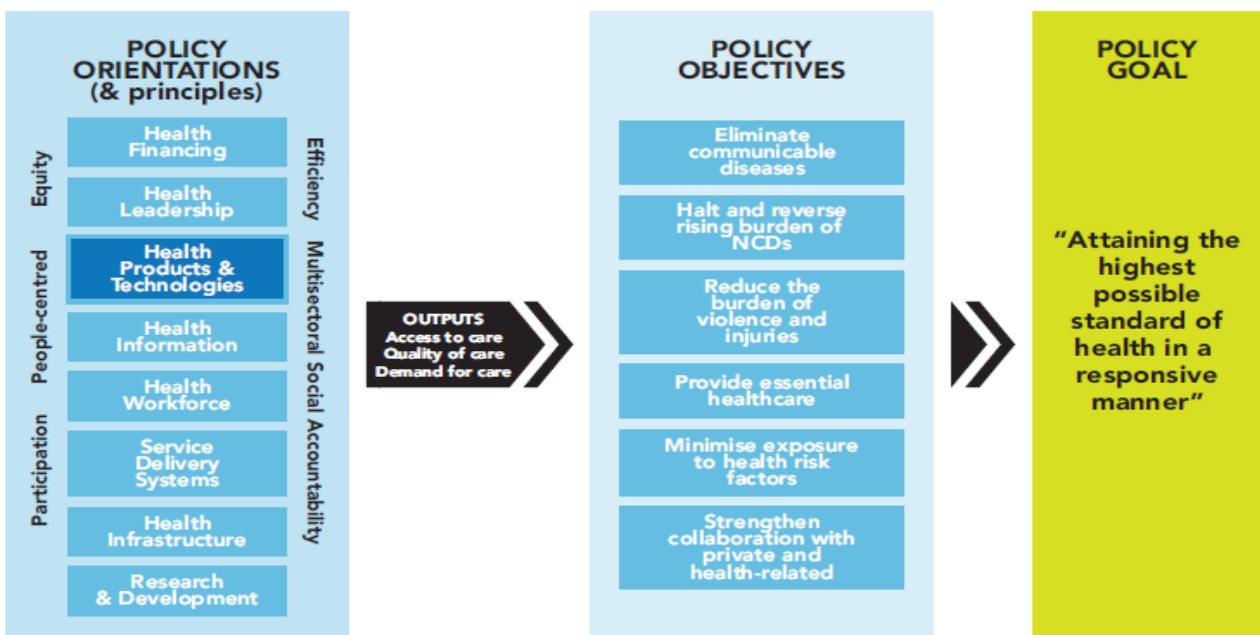


Figure 2: Health Policy Orientations, Objectives, and Goals (HPT Supply Chain Strategy 2020-2025).

The national government's mandate entails the formulation of health policies, management of the national referral hospitals, capacity building and technical support to the counties. The county governments are responsible for the implementation of the health policies at grassroot level and managing health facilities. There are six health sector service delivery levels in the country. Level 1 (Community Units) entail to all the services provided directly to households; Level II (Dispensaries) offer basic outpatient, eye-clinic, mobile clinic, dental care related problems and home-based care services; Level III (Health Centers) offer comprehensive curative, preventive, promotive and rehabilitative health services including maternity services. Level IV (Primary Sub-County/County Hospitals) complement the primary care level by providing specialized/referral services to allow for a more comprehensive package of close to client services; Level V (Secondary - County/Regional hospitals) provide a more comprehensive set of services, including highly specialized services, together with internship training services for medical staff, research and serve as training centers for paramedical staff; and Level VI (Tertiary National Referral Hospital) provide highly and super specialized services including specialist teaching and research. The Pharmacy and Poisons Board (PPB) regulates the HPT sector in Kenya.

The Universal Health Coverage (UHC) Policy 2020 – 2030 anchors UHC for all, an initiative that aims to address inequity and supporting the attainment of favourable health outcomes. The policy's objectives are (a) to strengthen access to health services, (b) ensure quality of health services, (c) protection from the financial risks of ill health and to (d) strengthen the responsiveness of the health system. Therefore, robust local manufacturing of HPT is one of the ways in achieving the objectives of the UHC policy by promoting accessibility, affordability, adequacy and quality of HPT.

b) Health Products and Technologies (HPTs) market overview

A healthy population is a key driver of socio-economic development of Kenya. The Kenya Constitution and Vision 2030 require the country to provide the highest attainable standards of healthcare to the entire population. This requirement is more urgent due to shifting health dynamics like the rise of climate-sensitive diseases, non-communicable and communicable diseases, increased health education and awareness among the population, and the emergence global pandemics e.g. COVID-19.

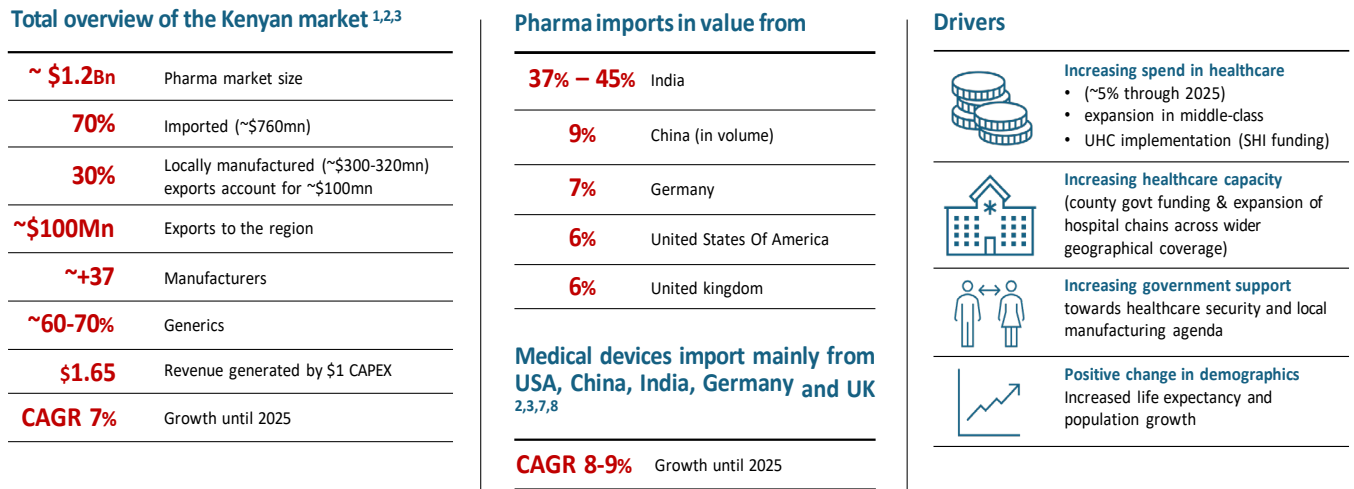
For HPT availability and sustainability, investing in local production is fundamental. HPTs comprise medicines, diagnostics, medical supplies, medical devices and technologies. HPTs make up approx. 28% of Kenya's national health care budget estimated at about Kshs.105.7 billion.

A report on Assessment of Local Manufacturing Capacity for Medicines in Kenya, evaluated the local medicine manufacturing landscape, scope, capacity challenges and growth opportunities, showing that despite having 694 medicine formulations manufactured locally, only 220 were in the Kenya Essential Medicines List (KEML) 2023, translating to 20% of the 1096 formulations in Essentials list. 56% of the 220 formulations each have only one local manufacturer.

The market shaping approach needs to be reviewed to address imbalances in product portfolio and value-pool prioritization of (e.g. *paracetamol has ~15 local manufacturers and ~200 imported brands*). While most locally produced formulations are tablets and oral liquids, complex products listed in KEML (e.g. *eye drops and injectable*) are less frequently produced due to unsustainable unit economics from a business sense. Sterile products' facility requires an initial investment of ~Ksh 800M (*plus a 20% cost escalation*) and 20% operating expenditure (OPEX) to keep facility running 24x7. Additionally, initial investment in GMP-controlled facility is in the range of Ksh 700M to 800M, an investment that can be recouped if market access assured. Market-shaping can accelerate growth of critical HPT value pools of interest, with the right support and goodwill for transparent GMP certification pathway that breaks down and diversifies product value pools and creation of matching sustainable financing mechanism.

Kenya's HPT market presents with mixed, non-linear scenario. The national HPT demand forecast for year 2021 showed that Kenya's public health facilities required HPT worth ~Ksh. 90 billion (*Ksh. 42 billion direct government procurement and Ksh 48.5 billion donor-funded procurement*). In 2022, HPT imports were estimated at Ksh 92.9 billion, and exports were estimated at Ksh 12.2 billion, indicating Kenya largely depends on imports to meet its local HPT needs. Although local HPT demand remains unfulfilled by local manufacturers due to systemic challenges, 70% of the pharma

products are imported while the country is the leading pharmaceuticals producer in East Africa and third largest exporter in Africa. Figure 3 shows the main sources of pharmaceutical imports, with India dominating at between 37% to 45% of pharmaceutical imports in Kenya by value. Most of the imported Medical Devices are sourced from Germany, China, UK, India and USA.



1. Kenya Pharmaceutical Industry – Diagnostic report 2020 (IFC, MOH, UKAID)
 2. African Pharmaceutical Manufacturing Industry: Opportunities and Challenges for growth 2022
 3. Statista 2023 – Kenya (<http://www.statista.com/outlook/cmo/otc-pharmaceuticals/kenya>)
 4. <https://www.trade.gov/country-commercial-guides/kenya-healthcare-medical-devices>
 5. <https://www.rvo.nl/sites/default/files/2021/05/2021-Kenya-Medical-Devices-eHealth.pdf>

Out of 306 PPB-registered Local Trade Representatives:

- 80% primarily import HPTs
- 7% dealt with Locally manufactured HPTs

Figure 3: Kenya Pharmaceutical Market Overview.

Figure 4 shows the main regional export markets for Kenya’s locally produced HPTs, as the country simultaneously contends with an underserved local demand that is sustained by imports mainly from India and China:

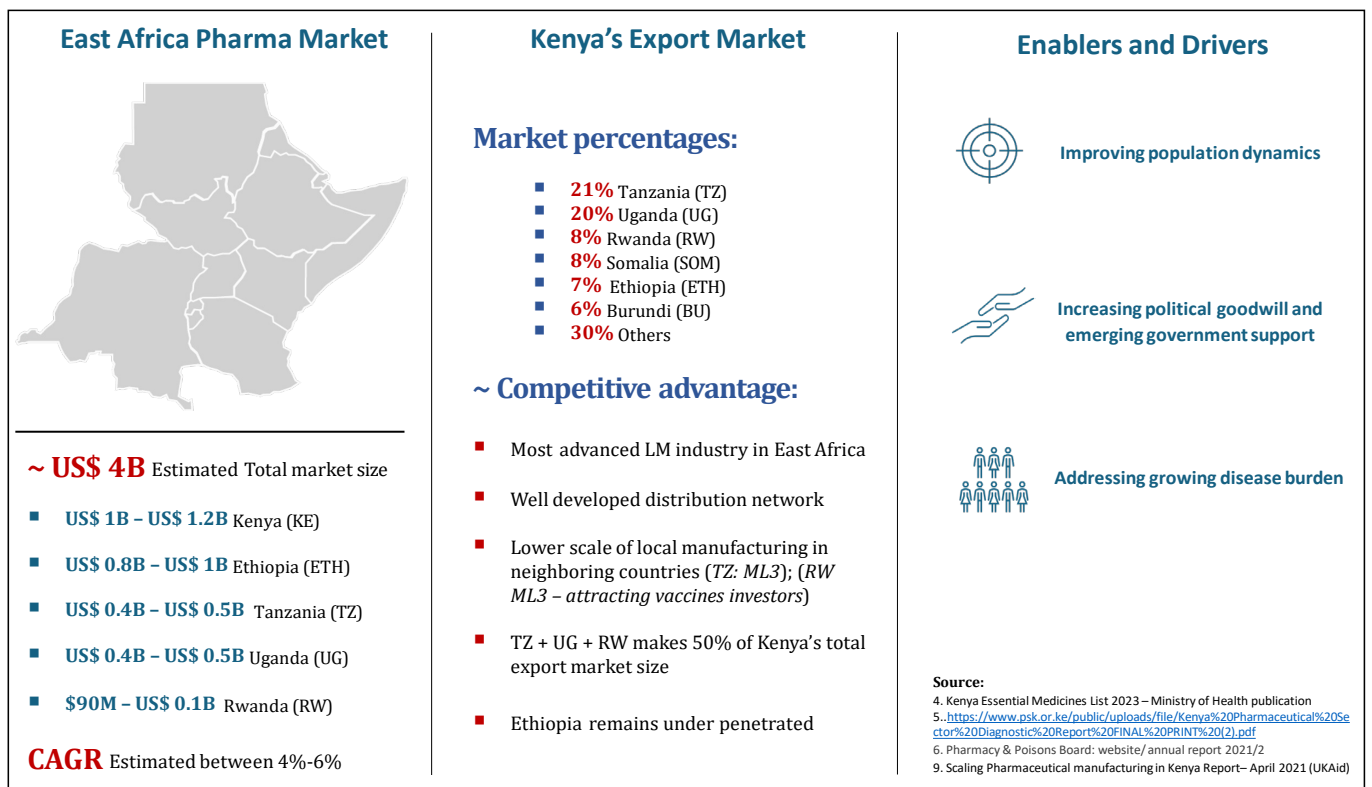


Figure 4: East Africa Pharmaceutical Market Overview.

A growing population and disease burden, a ready regional market, supportive national and regional policies create a compelling case for increased and diversified local manufacturing capacity. The Kenya Pharmaceutical Industry Diagnostic Report 2020 (IFC, 2019) noted that Kenya's market share in pharma export to COMESA, EAC and across Africa was 0.46% (US \$63 million) and recommended growing the share to 5% (US \$678 million) of \$13.6 billion addressable market for pharma products in Africa. However, there is need to demystify accessible and serviceable out of this addressable size.

Kenya Medical Supplies Authority (KEMSA) and Mission for Essential Drugs and Supplies (MEDS) are the two largest centralized procurement entities for HPT for public sector and faith based organizations, respectively. These two agencies source their HPT from local manufacturers and imports. However, most local manufacturers prefer to service private sector and export markets due to various challenges including delayed payments by public sector, higher local competition, favourable policies in other countries and inaccessibility of the local markets. Most manufacturers supplied only 25% of what they produced to the public sector. Local manufacturers who do not export their products cite bureaucracies in products registration in export markets, technical, financial, human resource and materials limitations, lack of Good Manufacturing Practice (GMP) certificates, and high local demand as the primary reasons.

Local pharma industry primarily focuses on formulation and repackaging of generic medicines, with limited research and development (R&D) efforts. Heavy reliance on imported APIs and excipients, mainly from India and China, exposes the sector to supply disruptions, foreign exchange fluctuations, and increased production costs. Moreover, while data on non-medicine product categories is limited, existing assessments indicate that local manufacturing capacity in these areas is generally low.

Overall, utilization of local manufacturing capacity is estimated at 40-60% of installed capacity hence the need for expanded production and diversification. Several incentives provided to support local manufacturing include: zero-rated or exemption from value-added tax and import duties for APIs or raw materials, machinery, and equipment used for pharmaceutical manufacturing, and waivers on custom duties for imported inputs and machinery for local manufacture of medicines. Additionally, key policy frameworks and strategies promoting the need for expanded local manufacturing include:

- Kenya's Vision 2030,
- National Industrialization Policy
- Kenya Health Policy (2014-2030)
- Universal Health Coverage (2020-2030)
- Kenya National Pharmaceutical Policy (KNPP) Session Paper 4 of 2012,
- Local content policy 2020
- Buy Kenya Build Kenya Strategy.
- Public Procurement and Asset Disposal (PPAD) Act No. 33 of 2015
- KEMSA Act 2013 (guides procurement of HPT)
- Pharmacy and Poisons Act Cap 244 (regulates HPTs)
- Public Financial Management Act, 2012 (guides budgetary allocations at national level)
- County Government Act, 2012 (guides budgetary allocations at national level)
- Regulations of donor agencies and priority programs also guide procurement of HPT in Kenya.

2

Situational and Stakeholder Analyses



2. Situational and Stakeholder Analyses

This section analyses the external and internal factors impacting Kenya's LM industry, a foundation for insights development for synthesizing key strategic issues as well as visioning and developing key strategic imperative therefrom. The analysis included SWOT and PESTEL around institutional, market dynamics, stakeholder feedback, and country competitiveness benchmarking. This guides the formulation of strategic interventions by grounding LM aspirations in evidence-based realities.

2.1 External Analysis

This sub-section examines contextual macro, micro, industry, and market factors impacting LM, strategic imperatives, opportunities for its growth and threats that may hinder its aspiration. This is critical to aligning Kenya's evolving LM reforms with ongoing and future regional manufacturing efforts for competitive position of Kenya as attractive and sustainable LM investment destination.

For a long time, global health has been premised on the principle of shared prosperity for mutual benefit among nations of the world. However, progressive economic policies to connect countries through facilitative trade policies and Regional Economic Communities (RECs) are being derailed by national "protectionist" policies, climate effects, and geopolitical shifts that gradually erode the social impact achieved in global and public health over the past years:

- Domestic and foreign aid is shrinking, forcing donors and governments to rethink financing for essential healthcare services, and thereby reducing available resources for activities that were previously funded through philanthropy and concessionary financing;
- The state of regional economies shows more individuals are struggling to make ends meet, thus a drop in available disposable household incomes, increasing the demand for health financing, and challenges in access and delivery of quality care and other social welfare services;
- Climate change variabilities continue to exert a crippling influence across sectors, resulting in unpredictable healthcare needs and responses. Climate-sensitive infections and epidemics are on the rise, exerting pressure on availability of emergency medical services and commodities, and resulting in avoidable expensive and expansive health programs due to new infections.

These factors imply Kenya must rethink how health programs, HPT, and services are delivered and made accessible in an increasingly resource-constrained, complex, and disruptive environment, by leveraging integrated data to develop innovative solutions in spite of a reduced resource envelope.

Simultaneously, HPT market is transitioning to value-based procurement as development partners signal shifts from direct procurement, system strengthening, and capacity building to expectations on government, counties and facilities to demonstrate sustainability in transition plans. With focus on domestic financing, it is incumbent upon Govt. to secure its limited resources within borders to grow LM industry through aggressive promotion of LM as an Import Substitution Initiative (ISI).

To achieve the above aspirations, enabling cross-sectoral and cross-border policies must be premised on the principles of congruence and harmonization for health sector, HPT industry, and LM agenda to gain traction. The following regulatory policies and strategy frameworks impact Kenya's health sector, HPT industry, value-chain sustainability, product development and commercialization, supply chain logistics, financing, and business models for local HPTs manufacturing:

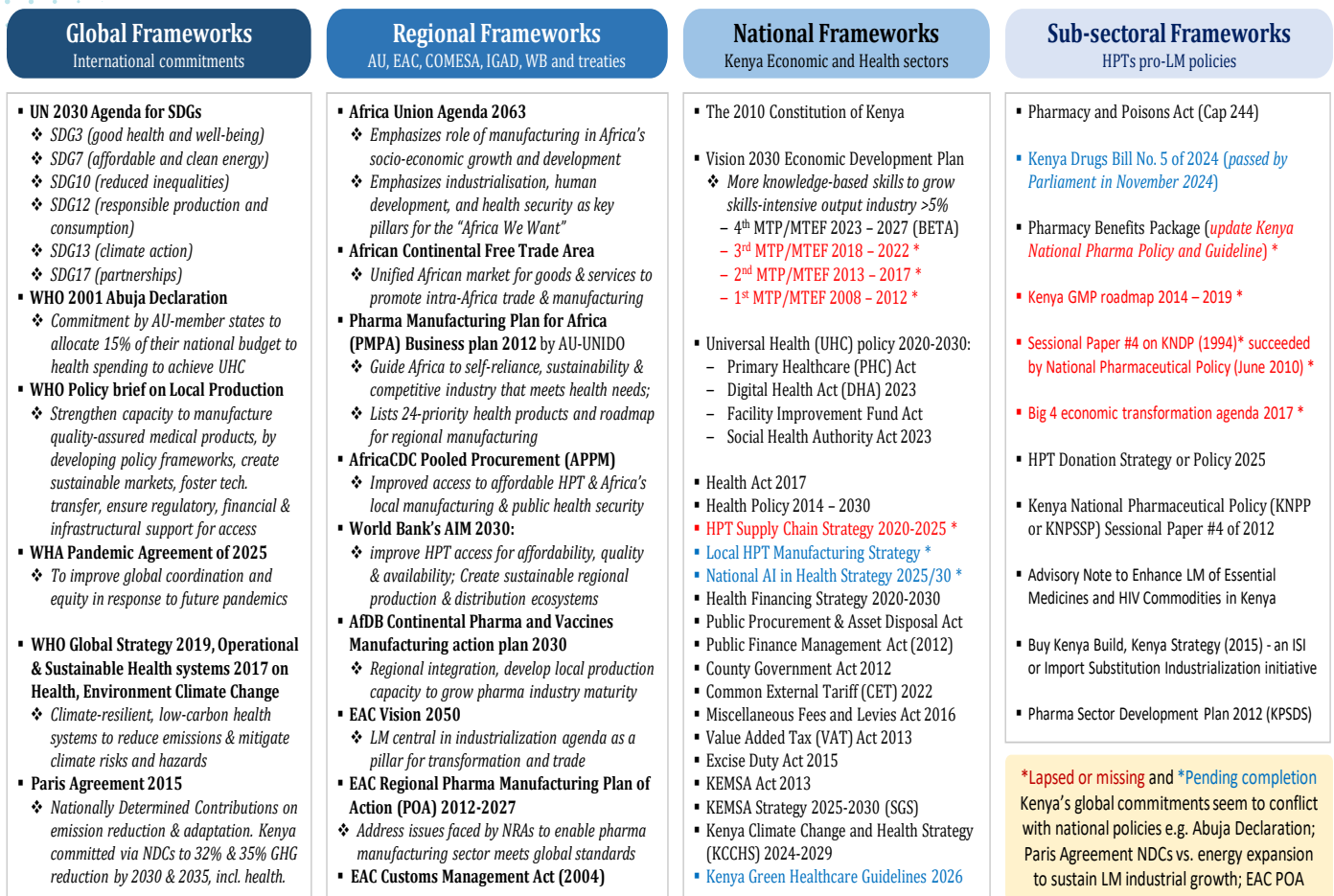


Figure 5: Regulatory Policies and Strategy Frameworks impacting Local Manufacturing.

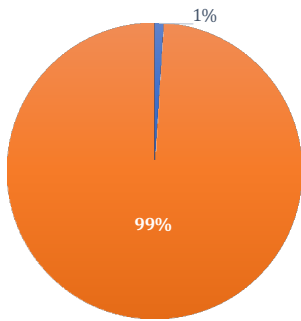
2.1.1. Global and Regional context

Globally, countries are prioritizing local manufacturing of health products and technologies (HPT) to enhance health security and reduce reliance on imports. India and China remain dominant players in the production of generic medicines and Active Pharmaceutical Ingredient (API), supported by policies such as India's Production-Linked Incentive (PLI) schemes and China's state-backed API industry. Countries like South Africa, Ghana, Brazil, and Egypt have strengthened local pharmaceutical industries through public-private partnerships (PPPs) and policy incentives, with initiatives such as Ghana's Pharma Park, Biovac in South Africa, and Egypt's domestic medicine production policies. Technology transfer and regional collaborations are also gaining momentum, with Rwanda and Senegal partnering with BioNTech in vaccine production, and Kenya establishing Kenya Biovax Institute. The WHO's mRNA vaccine technology transfer hub has engaged countries like South Africa, Argentina and Indonesia to enhance self-sufficiency. Regulatory harmonization efforts, such as the African Medicines Agency (AMA) and East African Community's (EAC) mutual recognition framework, are streamlining approval processes for locally manufactured products.

Various global initiatives are promoting Africa's self-reliance through local manufacturing of HPTs. The recent disruptive impacts of COVID-19 on HPT supply chains are accelerating an invigorated focus on growing local manufacturing. Figure 6 shows a market overview of Africa's manufacturing landscape and the continent's heavy reliance on importation across key product categories:

Vaccines

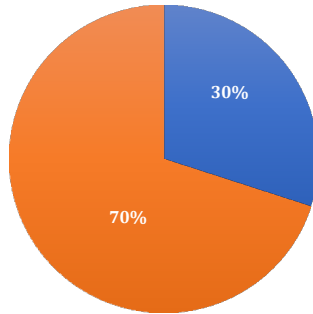
Africa relies on outside source to import 99% of its vaccines needs.



Key:
■ Importation
■ Local Manufacturing

Therapeutics

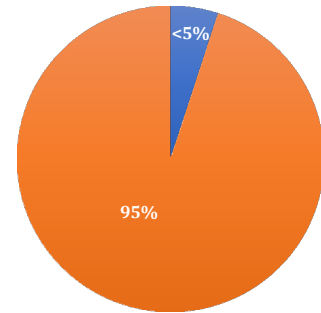
Africa has a low level of integration along its value chain which limits its manufacturing capacity



End-to-end approach:
 Supply, Demand and Enablers

Diagnostics and Medical Devices

Africa imports >80% of medical devices.



Increased political will and momentum due to COVID-19 disruptions has led to increase in local manufacturing initiatives

Figure 6: Africa’s manufacturing landscape for key HPT categories.

As a result, The World Health Organization (WHO) announced its support to Egypt, Kenya, Nigeria, Senegal, South Africa, and Tunisia to produce messenger RNA vaccines. In 2021, Partnerships for African Vaccine Manufacturing (PAVM) was established by the African Union (AU) and the Africa Centres for Disease Control and Prevention (Africa CDC) to enable vaccine manufacturing in 5 hubs across Africa and supply more than 10% of the required doses by 2025, more than 30% by 2030 and more than 60% by 2040.

Granting the governments the rights to issue compulsory licenses through TRIPS (Trade Related Intellectual Property Rights) agreement is the most progressive way in which the World Trade Organization (WTO) supports LMICs access to pharmaceutical products. UNCTAD (*United Nations Conference for Trade and Development*) is supporting the development of conducive investment policies, including regional medicines procurement, in the EAC region and selected East African countries to ensure the availability of essential antibiotics at national and regional levels. UNCTAD contributes to this objective through improved awareness and capacity of beneficiary national and regional policymakers. Further, US government’s new Health Cooperation Framework confers financial support to US-pharmaceutical manufacturing companies that are advancing LM in Africa through initiatives such as voluntary licensing and technology transfer. Local Kenya manufacturers willing to explore local markets to build capacities and local institutions and government have an opportunity to tap into regional initiatives, with support of government in areas like enabling regulatory systems reform in support of capacity utilization, growth, responsible and quality local manufacturing of HPTs.

i. UN 2030 agenda for Sustainable Development Goals (SDGs)

Adopted in 2015 by all UN member-states, the 2030 Agenda established 17 global SDGs aimed at peace and prosperity for people and the planet. Relevant to Kenya’s health sector and aligned to ESG and sustainability include the following SDGs:



Figure 7: ESG pillars aligned with SDGs impacting Kenya's Health sector and LM of HPT

Sustainability in LM is an emerging priority, with Germany and Scandinavian states leading in green production practices. October 2024 policy brief by GIZ reinforces LM's place in addressing inequalities in access to essential health care and HPTs. The report notes that robust pharma manufacturing sector in Africa is critical for the continent's public health and pandemic response. It further notes that COVID-19 pandemic revealed that without control over production, Africa remains susceptible to being disadvantaged in accessing HPTs due to unsustainability of global redistribution efforts in such critical times:

- Resilient infrastructure systems:** Continued importation, “just-in-case” emergency buffering to counter potential supply security concerns, and lack of donation policy amid weak fiscal and procurement practices, all combine to predispose Kenya and other LMICs to persistent PSM challenges due to obsolete, short-dated or expired HPTs. This culminates in accumulation of waste in the health supply chains, and environmental degradation of key determinants of population health (i.e. soil, water, air quality) as a result of unchecked disposal of expired products due to the lack of WHO-compliant but often expensive incineration facilities.
- Global (Paris) Treaty:** Though currently energy escalates unaffordability healthcare services, decarbonizing industries while striving to industrialize presents a sustainability conundrum for LM growth. Kenya committed to global climate framework that recognizes environmental impact, ESG and sustainability, and operational excellence. The Paris Agreement (2015) for Nationally Determined Contributions (NDCs) focuses on emission reductions and adaptation. Kenya committed to 32% and 35% GHG reduction by 2030 and 2035, respectively, including sector-specific measures for health, energy, agriculture, environment, and transport. To this end, and as part of Climate Action, WHO Global Strategy on Health, Environment and Climate Change (2019) is the operational framework for building climate-resilient and low-carbon health systems, and LM will be subject to this framework.
- Health access equals Energy access:** Africa is relatively low-carbon emitter, averaging 1 metric ton of CO₂ per capita against global average associated with Paris Agreement of 2.3 metric tons of CO₂ per capita. Africa already within limits targeted by Paris climate treaty or compliance frameworks. However, the pursuit of economic growth and industrialization is synonymous with energy use. Local Manufacturing will likely exacerbate emission risks due to intensive energy (e.g. associated with API extraction) which will impact SDGs 7, 12, and 13.

ii. Millennium Declaration (2001 Abuja Health Declaration by AU-member states)¹

A consolidated declaration of commitment and solidarity by 189 African heads of state adopted as the Millennium Declaration designed to improve social and economic conditions in the world's poorest nations by 2015. As a result, a set

¹ <https://iris.who.int/bitstream/handle/10665/341162/WHO-HSS-HSF-2010.01-eng.pdf>

of eight goals were devised, drawing on the Millennium Declaration, as a way of tracking progress. Three of these relate specifically to health while two more had health components. In April 2001 Heads of AU-member countries committed to set a target of allocating >15% of their annual budgets to improve their health sector. Simultaneously, donor countries were urged to “*fulfil the yet to be met target of 0.7% of their GNP as official Development Assistance or ODA to developing countries,*” drawing attention to the shortage of resources needed to improve health in LMICs/LICs. The median level of general government health expenditure from domestic resources (GGHE-FS)³ in AU member-countries then was ~\$103 with a thousand-fold difference between the minimum (US\$0.38) and maximum (US\$380). In terms of ODA, five of the 22 donors (then) reporting to the OECD were already giving at least 0.7% of their Gross National Income (GNI) with an unweighted average of 0.4%.⁴

Kenya’s total budget allocation to health as a percentage of total national and county budgets rose by 3.7% over 7 years, from KES 147B in FY 2012/13 (*pre-devolution*) to KES 216B in FY 2019/20 (*pre-COVID*). However, this is still far below the 2001 WHO Abuja Declaration to commit 15% of national budgets to health. 25 years later, only 4 of 54 African states met the threshold.

iii. Africa Union’s Agenda 2063

Aligned with priorities of Kenya’s BETA and MTP-IV, Agenda 2063 aspires for prosperous Africa based on Sustainable Development and Inclusive Growth, with broader goal of: “*Environmentally sustainable and climate resilient economies and communities, with priorities in sustainable consumption and production; renewable energy; and climate resilience.*”

Agenda 2063 emphasizes the role of manufacturing in socio-economic growth and development of Africa. However, this recognition has not translated to a robust manufacturing sector growth, with issues including overreliance on imported raw materials, unfavourable policies, structural adjustments, Africans’ preference for imports due to perceived higher quality, political instability, resulting in Africa as a net importer. Approx. 70% of Africa’s pharmaceutical needs are imported despite local production existing in about 50% of African countries, as only 8 countries account for 85% of Africa’s pharmaceutical manufacturers.

Some initiatives to enhance intra-Africa trade and boost manufacturing include establishing the African Continental Free Trade Area (AfCFTA), the world’s largest free trade area by membership with a market of over 1.4 billion people. AfCFTA presents a unified market for goods and services across Africa which, when effectively harnessed, will unlock the manufacturing potential among other socio-economic benefits. Individual countries have also been implementing an economic strategy where they prioritize domestic production as Import Substitution Industrialization (ISI) to grow local manufacturing sectors, reduce reliance on imports and foster industrial growth. The ISI’s include Kenya’s “Buy Kenya-Build Kenya” strategy, “Buy Malawi” Strategy in Malawi, “Proudly South African” campaign, and the “Buy Naija and Promote Naira” campaign in Nigeria – all geared towards encouraging their respective citizens to consume locally produced goods.

Local HPT manufacturing mirrors general manufacturing trends in Africa, remaining low despite the political goodwill from African governments. Low manufacturing is attributed to, inter alia, lack of risk-capital for investment financing, regulations, standards and conformity assessment procedures are not harmonized, fragmented markets, reliance on donor and global supply chains, and lack of harmonized. This is on the backdrop of unique challenges that include high disease burden that is misaligned to the dynamics of the global pharmaceutical markets, vulnerability to supply chains disruptions, unaffordability and low accessibility to HPT.

The 2025 report on 24 Priority Medical Products and Roadmap for Regional Pharmaceutical Manufacturing in Africa shows that 70-80% of Africa’s medical needs are met through imports. It identifies 24 key medical products for addressing

² The Abuja declaration quoted the target of 0.7% GNP (many donor countries express their targets in terms of GNI).

³ WHO Abuja report presents general government health expenditures from exclusively domestic finance sources (GGHE-FS)

⁴ <http://www.oecd.org/dataoecd/43/56/2507734.pdf>

the region's high disease burden and outlines a strategy for developing a self-sufficient, robust pharmaceutical sector. The strategy emphasizes **strengthening regulatory frameworks, fostering public-private partnerships, investing in LM, and promoting regional collaboration**. The focus is on high-need, high-impact products that address diseases disproportionately affecting Africa while creating economic opportunities.⁵

The African Pooled Procurement Mechanism (APPM) under Africa Centres for Disease Control and Prevention (Africa CDC) is promoting improved access to affordable HPT, a robust local HPT manufacturing and public health security in Africa. APPM's unique value proposition is "a strong collective bargaining power and local HPT manufacturing at global standards for Africa to reduce costs of access and achieve supply security. The mechanism is tailored to the continent's needs and is being rolled out in a phased approach both in scope and complexity. The strategic results envisaged by the APPM for member states include: -

- *Equitable, ethical and sustainable access to quality and affordable HPT through effective collective bargaining and strategic procurement approaches;*
- *Developed local and regional markets for HPT;*
- *Emergency response health products by leveraging African suppliers and healthy markets where there is partnership to ensure sustainability of global HPT markets and prevent the negative consequences of competitive buying.*

The APPM is, thus, an integral opportunity for Kenya's LM to tap into strategic positioning within East Africa both in HPT manufacturing and exports capacity.

African Development Bank (AfDB) also avails an opportunity for Kenya to develop and accelerate local HPT manufacturing. AfDB's 2030 Continental Pharmaceutical and Vaccine Manufacturing Vision and Action Plan, a 10-year blueprint, has the pillar to "**increase the maturity of the pharma industry by supporting the development of local production capacities**", with enablers including:

- *Regional logistics integration to foster intra-African trade and creation of trade hubs;*
- *Implementation of quality industry standards;*
- *Seeding the creation of R&D capacities focusing on Africa specific diseases and needs*
- *Paving the way for increased vaccines manufacturing in the continent.*

AfDB's plans to invest ~US\$3.1 billion by 2030; \$100 million per year to finance the development of the pharmaceutical industry directly and allocating about a further \$200 million annually to support infrastructure development to help ease logistics and support aspects of supply chain.

Latest development indicates AfDB, in partnership with the Gates Foundation, have previewed a proposed plan for new financing facility for health products on the African continent. **The Health Commodity Financing Plan** is intended to create an invoice discounting facility to help de-risk delayed payments associated with public sector and ease the working capital challenges faced by local HPT manufacturers as a result of extended outstanding debt from governments and public sector organizations. Since such DFI facilities usually take an average of 2 years to activate, this provides Kenya ample time to prepare to harness this facility for local HPT manufacturers when the initiative becomes active from around July 2028 onwards.

iv. East Africa Community (EAC) Vision 2050

An instrument to improve quality of life in the region through increased competitiveness, value added production, trade and investment, and aim for a prosperous, secure, competitive, and politically united region, with a major aspect being a robust health sector that provides 100% access to health. Specific strategies are: UHC, Health Systems Strengthening, Pharmaceutical Industry Development, Regional Collaboration, Promoting Healthier Lifestyles, and addressing emerging

⁵ <https://www.nepad.org/publication/24-priority-medical-products-and-roadmap-regional-manufacturing-africa>

Health Threats. This is through initiatives like setting up regional medical diagnostic centres, a rapid response mechanism for epidemics, and sentinel surveillance sites. It recognizes a healthy population is essential for economic development and regional integration. Further, it envisages the EAC Vision as the basis for defining strategies, policies and programmes to achieve and sustain key pillars of EAC integration as stipulated in the Treaty for the establishment of the EAC and to facilitate the realization of the African Economic Community.

Industrialization is one of its key pillars for driving transformation and enhancing trade with HPT manufacturing as its central agenda. Federation of East African Pharma Manufacturers (FEAPM) in its 2019 report proposed measures to boost local pharmaceutical manufacturing, measures which align with recommendations from several related studies and hold potential to enhance the local HPT manufacturing sector. These measures include:

- *Imposing a 25% import tariff on medicines that have sufficient local capacity;*
- *Removal of duties on raw materials, packaging, pharmaceutical equipment, and spare parts;*
- *20% price preference margin for locally manufactured pharma products in public tenders;*
- *Equal treatment for all LMs in EAC region on national incentives and procurement preferences;*
- *Harmonizing medicine registration processes across EAC member states and streamlining the implementation of pharmaceutical sector support across the region.*

Further, the 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action (2017–2027) aims to address key challenges faced by national medicines regulatory authorities (NMRAs) in East Africa for pharmaceutical manufacturing sector meets global standards. Proposed measures to foster a self-sufficient and competitive pharmaceutical manufacturing sector in EAC include: -

- *Reducing regional dependency on HPT imports from 70% to 50%,*
- *Increasing local procurement of HPT by national agencies by 50%*
- *Expansion of coverage of endemic diseases to over 90% by broadening the product portfolios of local manufacturers.*
- *Enhancing capacity of local manufacturers for advanced pharmaceutical formulations, including small volume injectable and complex tablets;*
- *Boosting R&D, including integrating traditional medicines into local manufacturing;*
- *Strengthening intellectual property rights (IPRs), technology transfer, and knowledge sharing to attract investments in areas like vaccine and biosimilar manufacturing.*

2.1.2. National context

Local HPT manufacturing plays a crucial role in socio-economic development through self-reliance, creation of jobs, foreign exchange earnings, and attracting foreign direct investment. However, its continued international competitiveness requires government support through reforms program.

National policies that influence local manufacturing include: Vision 2030, Health Act 2017, Kenya Health Policy 2014-2030, UHC policy 2020-2030, Public Finance Management Act 2012, Pharmacy and Poisons Act (Cap 244), County Government Act 2012, Value Added Tax (VAT) Act 2013, Excise Duty Act 2015, EAC Customs Management Act (EACCMA) 2004, Miscellaneous Fees and Levies Act 2016, Common External Tariff (CET) 2022, Kenya National Pharmaceutical Policy Sessional Paper 4 of 2012, and Public Procurement and Asset Disposal Act (PPADA) 2015. Further, regularly updated essential HPT list is critical in UHC. Below are the implications of these policies and legislations.

i. Constitution of Kenya 2010

A social contract between the people of Kenya and the government. Article 43 of the Constitution of Kenya (2010) entitles the citizens to right to health which encompasses: "*the highest standard of healthcare.*" The right to health is a fundamental human right guaranteed by Article 43(1)(a): "*every person has a right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care*"; and Article 43 (2): "*a person shall not be denied emergency medical treatment.*" Similar provisions are contained international and regional human rights instruments e.g. the International Covenant on Economic, Social and Cultural Rights and the African Charter on

Human and People's Rights, both of which Kenya has ratified. To meet these national and international obligations, Kenya obligated to take legislative, policy and other measures including setting standards to achieve the progressive realization of the right to health. Devolution of key health services to county governments is a progressive realization of this right, promoting access to health services across Kenya, addressing bureaucracy in provision of health services, promoting efficiency in health service delivery; and addressing low quality of services.

ii. Kenya Vision 2030

Twenty-two (22) year long-term economic blueprint that guides Kenya's development planning since 2008, with a strategic vision of a globally competitive, prosperous country with high quality of life. It prioritizes achievement of sectoral objectives including meeting regional and global commitment, with implementation anchored in successive 5-year Medium-Term Plans (MTPs): - *First MTP 2008-2012; Second MTP 2013-2017; Third MTP 2018-2022 and Fourth MTP 2023-2027*. Implementation of these MTPs has resulted in phenomenal economic growth, leading to the attainment of the Lower Middle-Income Country status in 2014.

However, Kenya is yet to realize key milestones on the journey toward Vision 2030 goals, partly due to internal and external challenges, like climate change (e.g. *prolonged droughts, and invasion of pests and diseases affecting performance of the agriculture sector*); after-effects of COVID-19 on global supply chain; exchange rate volatility; rising interest rates; and narrow fiscal space, and the Middle East conflicts. MTP IV is the last 5-year Medium-Term Plan whose end will leave only two (2) years to the conclusion of Vision 2030, ushering in an opportunity for reflection on the approach for the next long-term development plan for Kenya.

Published in 2007, this blueprint indicated Kenya's manufacturing sector as largely dominated by basic products, with only 5% involving skill-intensive outputs like pharmaceuticals. Challenges cited in the blueprint in relation to local manufacturing included:

- *High input costs (raw materials, labour, unreliable and expensive energy, poor infrastructure);*
- *Low productivity levels due to declining capital investment and low skilled workforce;*
- *Inefficient flows of goods and services; and*
- *Unfavourable business environment characterized by poor regulation, weak trade agreements, lack of rigorous legal enforcement, incidences of insecurity, and limited access to capital.*

Key aspects in Vision 2030 implementation included the need for more knowledge-based skills to develop knowledge-based economies (KBE) through application of high technology, and science, targeting areas like pharmaceuticals, scientific instrumentation, ICT, and flagship projects in industrial, manufacturing and SME parks and zones to provide infrastructure and services for stimulating the development of the manufacturing sector. Across MTPs I to IV (2008 to 2027), key pharmaceutical challenges that are still yet to be addressed to date include:

- *Local manufacturing of basic products and narrow export base;*
- *Inadequate, costly and unstable supply of energy;*
- *Lack of investment in innovation, R&D and use of obsolete technology;*
- *Limited access to affordable long-term financing;*
- *Poor linkages between training institutions and the industry;*
- *Existence of non-tariff barriers, unfavourable rules of origin and competitive products.*

Findings from 2024 Local HPT Manufacturing Capacity Assessment confirmed these challenges still persist, stating that improving infrastructural, Export Processing Zones (EPZs) and Special Economic Zones (SEZs) were meant to offer incentives. However, export-focused requirements and compliance cost remain prohibitively high, diverging from aspirations of EAC Vision 2050 and limiting broader pharmaceutical sector participation. Table XX under the Internal Analysis (Industry Economics sub-section) shows that only ~13% or 4 out of 30 HPT manufacturers in Kenya (3 *pharma and 1 medical devices*) established their operations in EPZ, indicative of restrictive export requirements and high compliance costs. This is despite the constraint of poor payment by the local public sector which offers the biggest market share for HPT usage.

Despite such barriers, there has been growth with locally manufactured medicine formulations in the Kenya Essential Medicines List (KEML) rising from 116 in 2020 to 223 in 2024, although this still accounts for just 20% of public sector needs. New manufacturers have also established operations in Kenya with 15 new pharmaceutical manufacturing companies established within a 20-year span, i.e. between 2004 and 2023 compared to 11 new companies over a 40-year span between 1953 and 2003.

Kenya however continues to lag in production of complex pharmaceutical formulations and active pharmaceutical ingredients (APIs) due to inadequate innovation, limited technology and technology-transfer opportunities, and weak market assurance mechanisms.

iii. Bottom-Up Economic Transformation Agenda (BETA)

BETA is the government's economic strategy to revitalize sectors with high impact on economic recovery e.g. healthcare, agriculture, housing, digital economy and MSME. This will be achieved through targeted investments in five core pillars that includes Healthcare. BETA appropriately situates Local HPT manufacturing as it is supported by strategic investment intervention in good governance, manufacturing, infrastructure, and environmental sustainability. BETA aims for economic turnaround, equitable economic empowerment at grassroots, and inclusive growth through a value chain approach, with the main objectives including:

- *To bring down the cost of living;*
- *To eradicate hunger and create jobs;*
- *To improve foreign exchange balances;*
- *To expand the tax base;*
- *Inclusive growth.*

iv. The Fourth Medium Term Plan (MTP IV) 2023-2027

MTP IV themed 'Bottom-Up Economic Transformation Agenda for Inclusive Growth' translates BETA aspirations into concrete priority interventions for implementation through five sectors:

- *Infrastructure;*
- *Finance and Production;*
- *Governance and Public Administration; and*
- *Social; Environment and Natural Resources.*

MTP-IV advances **inclusive green growth** as one of the strategic interventions to manage cost of living, address public debt burden, and ensure effective policy implementation. As the last five-year medium-term plan of the Vision 2030, MTP IV is primed as a catalyst for achieving projected economic growth of 2.5% over 5 years driven by its key priorities which includes, among others, strengthening healthcare by delivering Universal Health Coverage (UHC), Investing in the digital super highway and creative economy, and transforming MSME economy. Currently, aspirations and priorities of Vision 2030 and BETA planning approach have been aligned through MTP-IV.

2.1.2.1. Health Sector context

Kenya has many guiding policies, laws, regulations and strategies with some having health sector-wide coverage while others are specific to the HPT industry. The key policies include:

i. Kenya Health Policy (2014 – 2030)

Policy's orientation 6 is on Health products and technologies. Investments under this orientation will ensure that effective, safe, and affordable health products and technologies are available and rationally used at all times, while moving towards maintaining a strategic national health products and technologies (HPT) reserve. This will be attained through the development and implementation of a national HPT policy and relevant regulatory frameworks that will further elaborate on the following strategies: Strategy VI under the policy is promoting local production, research, and innovations of essential health products and technologies; this shall be done in a manner that advances universal access and promotes national competitiveness.

ii. Kenya Universal Health Coverage Policy (2020-2030)

The UHC policy acknowledges the need to strengthen the local manufacturing of HPT noting that the availability, accessibility, quality and pricing of medicines, vaccines and other HPT is a key component and challenge to the success of UHC. The policy thus advances the need for strengthening the capacity for accurate forecasting and quantification of HPT at facility, county and national levels in line with national guidelines. It roots for optimal pricing, improved quality, economies of scale through transitions to open systems, and efficiency by emphasizing strong pooled purchasers of HPT like KEMSA.

Critical in shaping health sector's efforts toward UHC include the following two strategic plans:

iii. Kenya Health Financing Strategy (2020-2030).

The goal of the Kenya Health Financing Strategy (2020-2030) is to “ensure adequacy, efficiency and fairness in financing of health services in a manner that guarantees all Kenyans access to the essential health services that they require”. HPT are part of the essential health services. Recognizing the intersectionality of providing affordable, equitable and quality healthcare services, the Strategy was designed to have suitable governance and coordination structures for implementation, promotion of transparency and accountability. The strategy's emphasis is prioritization of UHC in the reform agenda by national and county governments, citizenry and private sector players. Further, the strategy is geared towards revenue raising, pooling and management and utilization in purchasing essential services.

iv. Health Products and Technologies Supply Chain Strategy 2020-2025 (Outdated).

Aimed to improve coordination, provide strategic direction, guide investments, and effective decision-making across Kenya HPT supply chain. With a vision for a sustainable, resilient and responsive HPT supply chain system, the strategy's six pillars were:

- *Enhance capacity for governance, regulation and quality assurance.*
- *Establish & sustain robust HPT selection, quantification, procurement and distribution system.*
- *Collaborative partnerships at all levels for effective resource mobilization and implementation.*
- *Embrace and adopt Information Communication Technology in all aspects of HPT supply chain.*
- *Scale-up capacity for research, local production, and full exploitation of Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities for HPT; and*
- *Strengthen human resource management and development for HPT supply chain.*

2.1.2.2. Pharmaceutical Sub-sector context

The key laws and regulations that influence HPT manufacturing in Kenya include the Health Act 2017, the KNNP Sessional paper no.4 of 2012, various finance and taxation laws, Pharmacy and Poisons Act (Cap 244), Facilities Improvement Financing (FIF) Act 2023, Public and Procurement and Asset Disposal (PPAD) Act, and Kenya Medical Supplies Authority (KEMSA) Act, and Pharmacy and Poisons Board Act.

i. Health Act 2017

Section 67 of the Health Act 2017 provides guidelines for the management of HPT. Through the essential HPT lists including the Kenya Essential Medicines List (KEML), and the Kenya Essential Medical Supplies List (KEMSL) the government orients management of HPT to ensure access and affordability of essential medicines and other health products for the population.

ii. Kenya National Pharmaceutical Policy (KNPP) Sessional No. 4 of 2012

This aimed to promote local manufacturing of essential medicines to achieve self-sufficiency and expand pharmaceutical exports. However, its implementation over a 10-year period was limited, with only 30% of proposed interventions realized—*mainly in creating an enabling environment, enforcing GMP standards, and addressing counterfeit medicines*—while key actions like technology transfer, international accreditation, and harmonization of regulatory frameworks remained unimplemented. Key challenges identified included conflicting policies, over-regulation, high production costs, poor

infrastructure, limited skilled personnel, costly compliance requirements. The policy is under review to address these gaps and respond more effectively to broader HPT challenges, including quality, affordability, and supply chain dynamics.

iii. Pharmacy and Poisons Act (Cap 244)

Gives PPB mandate to implement appropriate regulatory measures to achieve highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices, imported, locally manufactured, exported, distributed, sold, or used, to ensure protection of consumers as envisaged by the laws regulating drugs in Kenya. Mandate includes registration and licensing of HPT professionals (pharmacists and pharmaceutical technologists) and facilities i.e. wholesalers, retail or manufacturers of HPT. Strengthening regulatory systems (e.g. *attaining ML3*) promotes globally accepted standards and increase acceptance of Kenya's HPT locally and globally.

iv. Public Procurement and Asset Disposal (PPAD) Act

Promotes local industry by requiring public entities to prioritize locally manufactured goods and services by registered firms, with preferential treatment extended to local agents. However, local agents are not necessarily local manufacturers. PPAD provides a margin of preference ranging between 6% and 20% based on Kenyan shareholding level and 10% for citizen-involved joint ventures. Despite these provisions, local manufacturers face stiff competition from imports due to higher production costs. As of April 2024, 80% of 306 registered local trade representatives listed by the PPB dealt primarily with imported medicines, while only 7% focused solely on locally manufactured products - undermining the intended procurement preferences.

v. Value Added Tax (VAT) Act of 2013

Raw materials for pharmaceutical manufacturers in Kenya are zero-rated while finished are tax exempt – meaning VAT on inputs cannot be reclaimed, affecting working capital. Most non-Active Pharmaceutical Ingredients (API) inputs like packaging materials remain taxable. Finance Act 2022 introduced VAT exemptions on plant, machinery, and select medical items to encourage local production, support R&D, boost vaccine manufacturing, and reduce treatment costs for terminal illnesses. Introduction of locally purchased element is meant to encourage investment in local purchases. Exemption on plant and machinery is also aimed at promoting research and development in the medical sector and spur the production of vaccines in Kenya.

vi. Excise Duty- Excise Duty Act 2015

Pharmaceuticals Inputs, raw materials and finished products are not subject to 35% excise duty to help keep medicine prices lower. However, Finance Act 2023 introduced significant tariffs — *Imported packaging materials at 25%, glass bottles and folded cartons, and 10% for plastics* —raising production costs. For years now, local manufacturers have frequently called for removal of these taxes on the basis that they significantly affect cost of finished product and thus impact affordability.

vii. Common External Tariff (CET) [2022 Version]

No import duty is charged for the majority of the pharmaceutical raw materials and finished products [East Africa Community Common External Tariff (CET) [2022 Version]. IDF (2.5%) and RDL (1.5%) are paid for finished pharmaceutical products. Inputs and raw materials imported by manufacturers of pharmaceutical products are exempt from IDF and RDL upon approval of the National Treasury on the recommendation of Cabinet Secretary for Health [Finance Act, 2022]. The Finance Act, 2023 made amendments to the import declaration fee (IDF) charged on imports, reducing IDF rate from 3.5% to 2.5% for all imported goods.

2.2 Internal Analysis

2.2.1. Industry Economics and Market Overview

⁶The manufacturing sector (which includes the HPT local manufacturing industry), grew by 2.8% in 2024, up from 2.2% in 2023, contributing 7.3% to Kenya’s GDP . The volume of output increased by 4.4% in 2024 compared to 2.8% in 2023, while formal employment rose by 1.9% to 369.2 thousand persons (accounting for 11.5% of the share of formal employment).

However, credit advanced to the manufacturing sector declined by 12% from KSh 639.4 billion in 2023 to KSh 562.9 billion in 2024, largely due to reduced lending from commercial banks even as development finance institutions expanded support to manufacturing projects by 19.7% to KSh 2.2 billion in 2024. Total approved credit to manufacturing sector in 2024 (~KSh 563 billion) is largely attributed to a mix of the following sector-specific credit financing performance: -

- Credit approved by Commercial banks (largest contributor) **decreased** to KSh 560.6 billion
- Credit approved by industrial financial institutions **increased** by KSh 0.4B to KSh 2.3 billion.
- Number of projects financed by development finance institutions **decreased** by 11 to 351 in 2024.
- Investment in EPZ manufacturing activities **increased** by 5.6% to KSh 34.1 billion in 2024.
- Cumulative investment value in EPZs **increased** by 15% to KSh 171.9 billion

Despite not attracting financing, production volume from non-food sub-sector had mixed performance with pharmaceutical output **increasing** in 2024 (on the backdrop of ~70% to 80% imports mostly from India, with only ~20% to 30% produced locally as illustrated in figure 8 below).

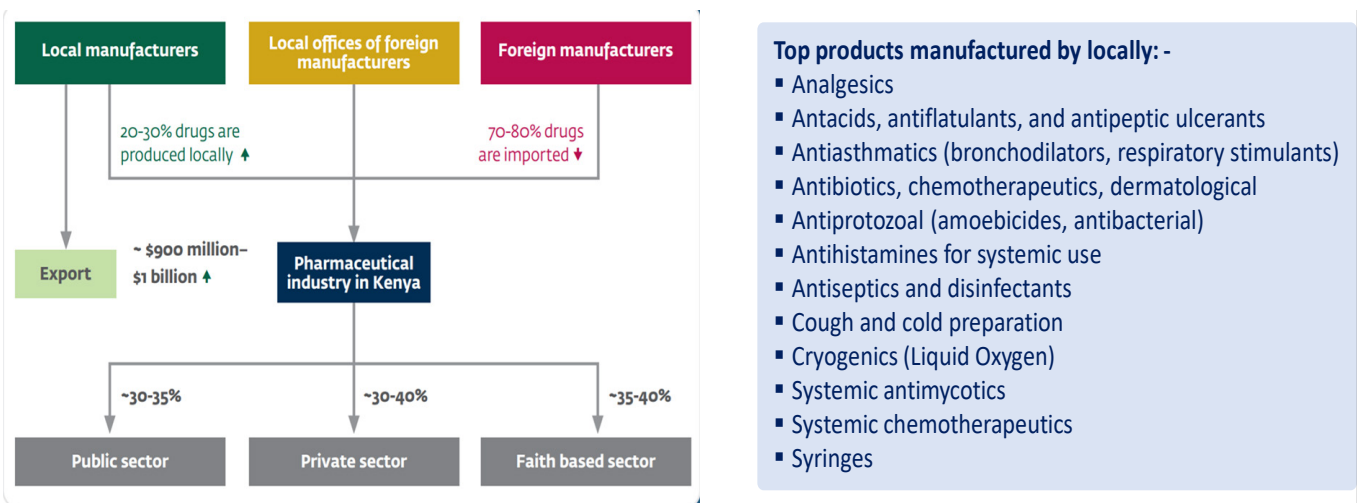


Figure 8: Landscape of Kenya Pharmaceutical Manufacturing, Import and Distribution

Table 2 shows the quantities and values of pharmaceutical products making up Kenya’s domestic exports and imports between 2019 and 2023, as well as the local Producer Price Index (PPI) – which measures the average change in price of products as they leave the factory.

⁶ Economic survey report (KNBS) 2025

Table 2: Quantities and Value of Pharmaceutical Imports and Exports and Producer Price Index (PPI)

Market	Metric	2019	2020	2021	2022	2023	2024
Imports	Volume (Tons)	32,378	39,389	30,182	34,825	37,079	38,159
	Value (Ksh -> million)	65,758	75,919	88,443	92,896	90,557	99,859
Exports	Volume (Tons)	12,577	13,258	11,864	12,485	18,809	19,319
	Value (Ksh -> million)	10,327	10,965	11,116	12,211	17,684	19,901
Net Imports <i>(calculated)</i>	Volume (Tons)	19,801	26,131	18,318	22,341	18,270	18,840
	Value (Ksh -> million)	55,431	64,954	77,326	80,685	72,873	79,958
Producer Price Index (PPI) - Local			107.85	120.34	154.76	159.58	143.17

Source: Economic Survey 2025 (KNBS) Tables 6.5 to 6.8 and Table 10.6

Figure 9 below is a derivative of Table 2. It shows that the effective Net-Imports utilized locally in Kenya (i.e. Imports less Exports) peaked between mid-2021 to mid-2022 at the height of COVID, followed by a slight drop mid-2023 then upward trajectory course correcting effects of COVID disruption on supply chain. Continued import dependency depict Kenya’s pervasive vulnerability to global shocks and their impacts on health supply security and achievement of UHC goals.

Differential or Local utilization of Net Imports (Imports minus Exports)

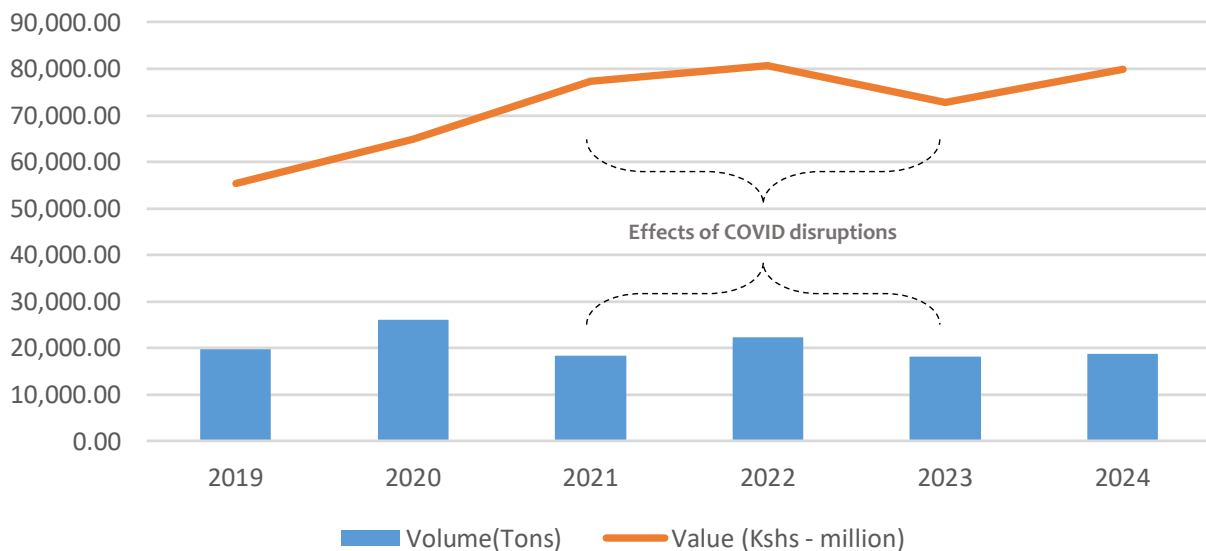


Figure 9: Effective local utilization of net imports

Additionally, Producer Price Index⁷ (PPI) for the manufacturing sector decreased from 140.20 in 2023 down to 139.04 in 2024, despite significant improvement in some of its sub-sectors like Agro-industry (9.8% growth) and Non-Metallic Mineral Products industry’s (30.44% growth). **The largest price drop was from the manufacture of Pharmaceuticals, Medicinal, Chemical, and Botanical Products, which dropped by 9.96%, despite pharmaceutical industry’s sustained volume growth which expanded by 2.5% in 2024 due to increased tablets and syrups production.**

Figure 10 below is a benchmark of the pharmaceutical industry’s 5-year trend analysis between the PPI of locally produced drugs *versus* effective local utilization of Net Imports. The trend shows consistent upward growth in value of net imports

⁷ Producer Price Index (PPI) is valued at basic prices and measures the average change in price of products as they leave the factory

and PPI of local products between 2020 and 2022 (despite volumes dropping in 2021 for net import, reflecting a possible value-for-money with import channel). This trend was followed by post-2022 decrease in Net Imports Value while PPI maintained only a slight increase, after which it abruptly decreased while Net Import Value grew. This inter-play needs further investigation to unlock any systemic factors crippling the local pharmaceutical value chain across Levels 1, 2, and 3.

While Pharmaceutical industry recorded the highest PPI drop from 159.58 in 2023 to 143.17 in 2024, Kenya’s overall inflation, as measured by PPI, contracted from 140.20 in 2023 to 139.04 in 2024. This further necessitates a robust value chain study for select HPT value pools of interest to filter out any embedded and embodied systemic, regulatory, and market traction factors that erode pharmaceutical industry’s value-for-money and return-on-investments.

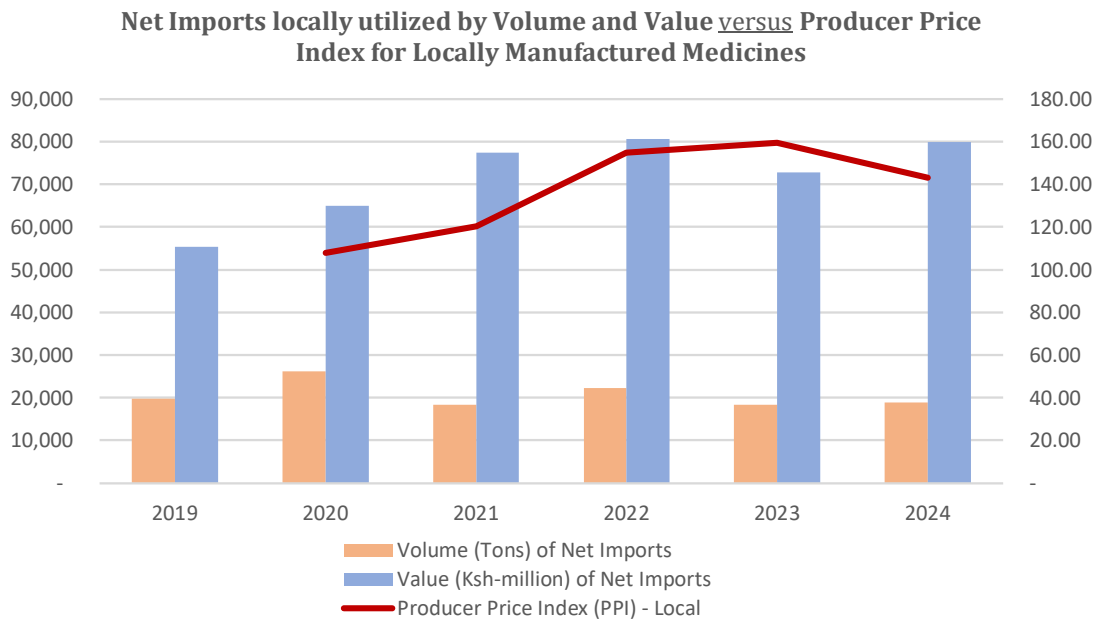


Figure 10: Producer Price Index of Local products versus effective local utilization of net imports

2.2.2. Industry Value-Chain and Business Model

Local Manufacturing Capacity Assessment report analysed HPT industry using the Pharmaceutical Value Chain (PVC) model, a set of critical, interconnected phases that HPTs go through for their development into the appropriate use by patients (product development to commercialization as shown in Figure 11).

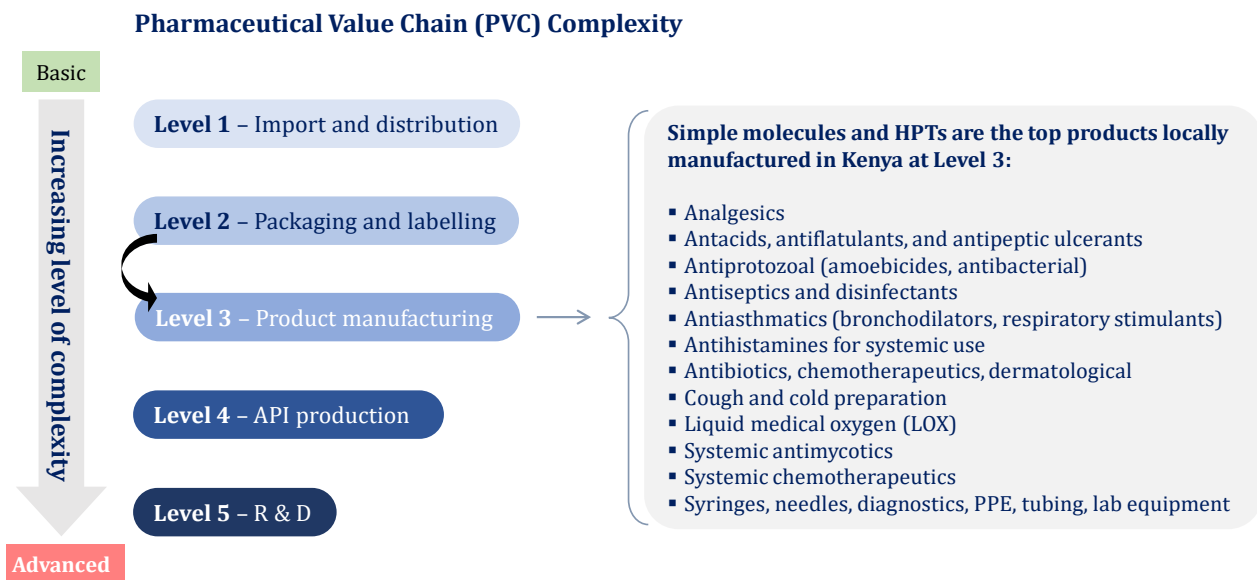


Figure 11: Kenya's Pharmaceutical Value Chain (PVC) model and top HPTs manufactured locally

Understanding PVC is key to aligning LM initiatives to the right resources in the drive towards efficiency, innovation, technological advancement, and market competitiveness. Figure 11 shows the five (5) levels of PVC model based on increasing level of complexity i.e. from basic (Level 1) to advanced (Level 5).

Figure 12 and Table 3 show actors in Kenya HPT industry as concentrated in PVC level 1-3, with none of LMs in API production, and only 19% - 22% (10 out of 53 or 44) product manufacturers in R&D across all HPT groups. While data is scanty on other HPT categories and inconsistent on registered manufacturers (i.e. 30, 37, 44, and 53 from various sources), there are 11 manufacturers in therapeutic nutritional feeds, 6 in traditional medicines, 4 in medical supplies, 10 in medical diagnostics, and 27 in medical equipment (informal sector artisans mainly involved in manufacturing less complex equipment that are not included).

Kenya Biovax is the only local actor in Vaccines R&D and manufacturing, but commercialisation is subject to PPB attaining ML3 status and Biovax attaining GMP and WHO-PQ compliance. There is need to develop specific interventions to integrate data and enhance the manufacture and growth of other HPT categories to support legitimate, qualified and compliant local manufacturers.

Currently, despite prevailing fiscal and non-fiscal incentives extended by government to bolster upstream level 4 (API production) and level 5 (R&D), the two PVC levels remain underexploited by local actors in key value-pool categories (Pharmaceutical, Vaccine and Medical Equipment) due to high capital and complex technology, with majority of the industry actors concentrated on importation and distribution, and fill-finish-package-labelling. Table 3 provides a view of local manufacturers in Kenya and their levels along the PVC based on available data.

Local Manufacturers mapped along Pharmaceutical Value chain (PVC) model

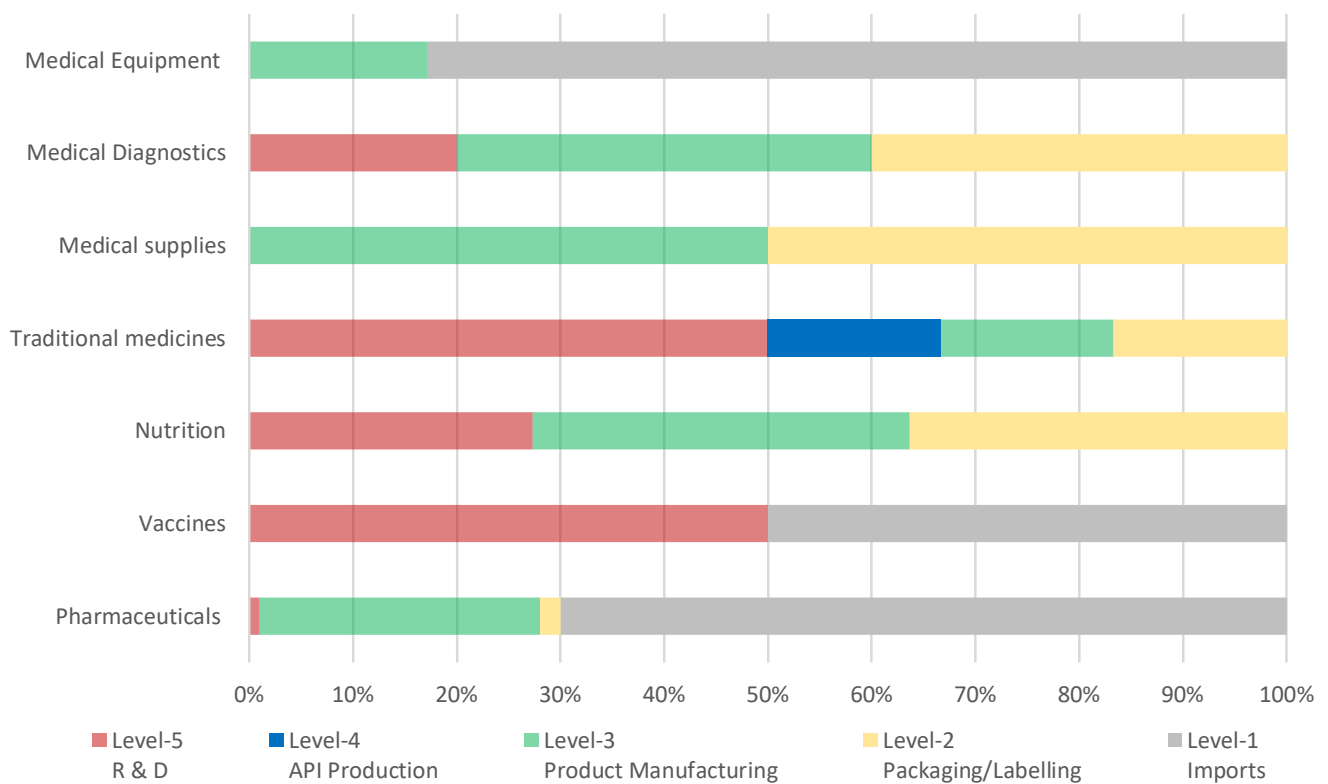


Figure 12: Local Manufacturers and Product categories along the PVC model

Table 3: Summary of local manufacturers and product categories along the PVC model.

Increasing level of complexity in the Pharmaceutical Value Chain (PVC) model -->					
Product category	Level-1 Import and Distribution	Level-2 Packaging & Labelling	Level-3 Product Manufacturing	Level-4 API and Raw material Manufacturing	Level-5 Research & Development
Pharmaceuticals	>70	2	27	-	1
Nutrition	-	4	4	-	3
Traditional medicines	-	1	1	1	3
Medical supplies	-	3	3	-	-
Medical Diagnostics	-	4	4	-	2
Medical Equipment	>24	-	5	-	-
Vaccine (KBI/Biovax)	1	KBI pilot	KBI pilot	-	1

Table 3 and Figures 12 indicate imports inadvertently displaces local capacity for R&D and new products development, thus confining Kenya’s HPT manufacturing industry to formative stages of small molecules (simple generics) and derailing technological advancement to complex generics. As Figure 13 below indicates, this makes Kenya uncompetitive outside East Africa in areas of Bioequivalence and regulatory strengthening for GMP compliance, which derails efforts in regional certification and compliance. Lack of PPB ML-3 status also limit progress toward commercialization of lot-release vaccines from Kenya Biovax.

While Level 4 and 5 confer significant fiscal and non-fiscal government incentives, they demand advanced technology, industry-aligned skills, intensive capital and infrastructure for the envisaged scale of delivery.

Strengthening upstream PVC level 4 and 5 is key to expanding the base and range of HPT value-pool and transitioning beyond simple molecules into complex generics and subsequently improving technological infrastructure while upskilling in line with Vision 2030 for transforming Kenya into a knowledge-driven economy. This will require approaches like syndicating stores of APIs (active pharmaceutical ingredients) across Africa to diversify supply chains for key HPT value pools and build capacity for LM.

Fully realising LM sovereignty is pegged on scaling PVC level 4 and level 5 to drive Import Substitution Industry (ISI) and counter the pervasive imports predisposing Kenya to global variabilities. Upscaling Bioequivalence and Pharmaceutical equivalence are enablers but demand intensive infrastructure, skills, capital and regulatory advancements, costs which are 100% underwritten by government incentives at level 4 and 5. Significant strategic relevance abound in PVC L4 (API production) and L5 (R&D) as critical components of LM that are foundational to transforming local and regional healthcare systems. This will consolidate the health sovereignty, self-reliance, industry growth, regional competitiveness, strengthen health value-chain, and enhance HPT security as vanguards against global market volatility.

Figure 13 shows the Small versus Complex Drug Landscape and Kenya’s LM industry maturity level. Drug products have been positioned on the basis of the challenge to assess pharmaceutical equivalence (PE) and bioequivalence (BE) of two drug products (i.e. reference product and its generic version). Conventional low-molecular-weight drugs that can be fully characterized are in orange (small molecules that dominate Kenya LM industry) and demonstration of their PE and BE is relatively simple. Biologics are shown in green and demonstration of their PE and BE is slightly more difficult. Complex drugs are shown in blue (NBCDs) or white (other complex drugs). For the majority of NBCDs, both PE and HE are difficult to demonstrate, owing to the inability to synthesize homo-molecular material, an unknown mode of action, and/or the difficulty to fully characterize the products. Albumin-bound nanoparticles and low-molecular-weight heparins are blue with a green outline (classification of these drugs varies globally)

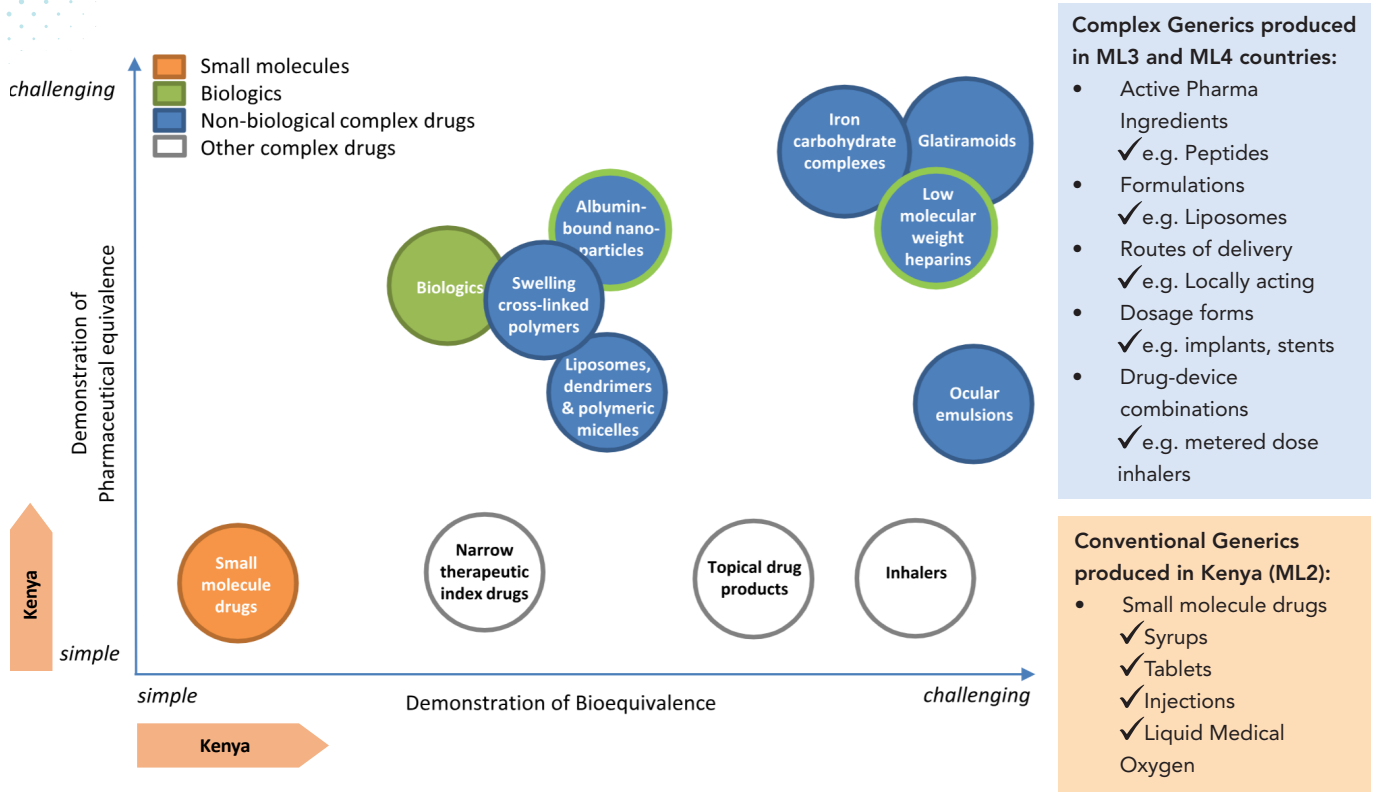


Figure 13: Simple vs. Complex Drug Equivalence and maturity of Kenya’s LM industry

2.2.3. Lifecycle for Vaccine Development, Manufacturing and Commercialization

Kenya Biovax institute is a government-owned, limited liability enterprise that was established in September 2021 under the Companies Act 2015. It is solely owned by the National Treasury and is mandated to carry out the following statutory obligations: -

- Manufacturing and commercialisation of vaccines, special therapeutics and diagnostics
- Support technology transfer and commercialisation of research output from research institutions and universities, etc.
- Support local pharmaceutical industries in development and production of quality and affordable health products.

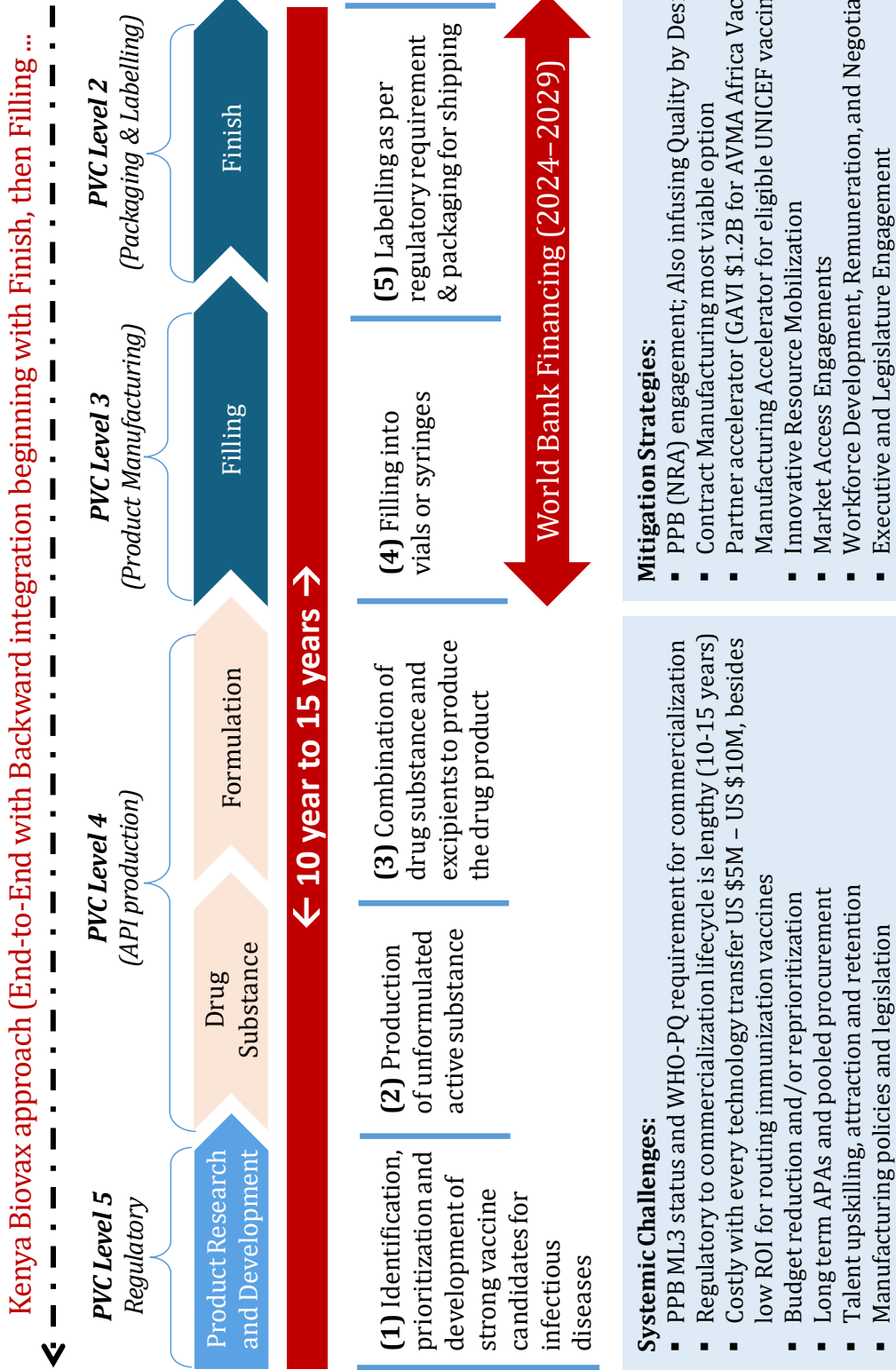
Rationale for the establishment of Kenya Biovax Institute include: -

- Preparedness and supply chain resilience (both local and global) against health emergencies
- Facilitate GAVI transition by December 2029 to sustain greater need for affordable vaccines
- Contribute to UHC and access to essential medicines
- Strengthen local manufacturing sector with job creation (as per Vision 2030 Economic pillar)
- Leverage on existing and potential know-how and skills

Balancing the public health mandate while ensuring long-term business viability remains an enduring and broader mandate and obligation of KBI whose portfolio includes the following: -

- Routine immunization
- Outbreak vaccines
- Biotherapeutics (insulin, anti-venom, monoclonal antibodies, gene therapies)
- Contract manufacturing arrangements for selected pharma, vaccines and biologics

Lifecycle for Vaccines product development, manufacturing, and commercialization



© Kenya Biovax Institute (2026)

Figure 14: Lifecycle ecosystem for Vaccines Development and Manufacturing

Kenya Biovax journey and evolution

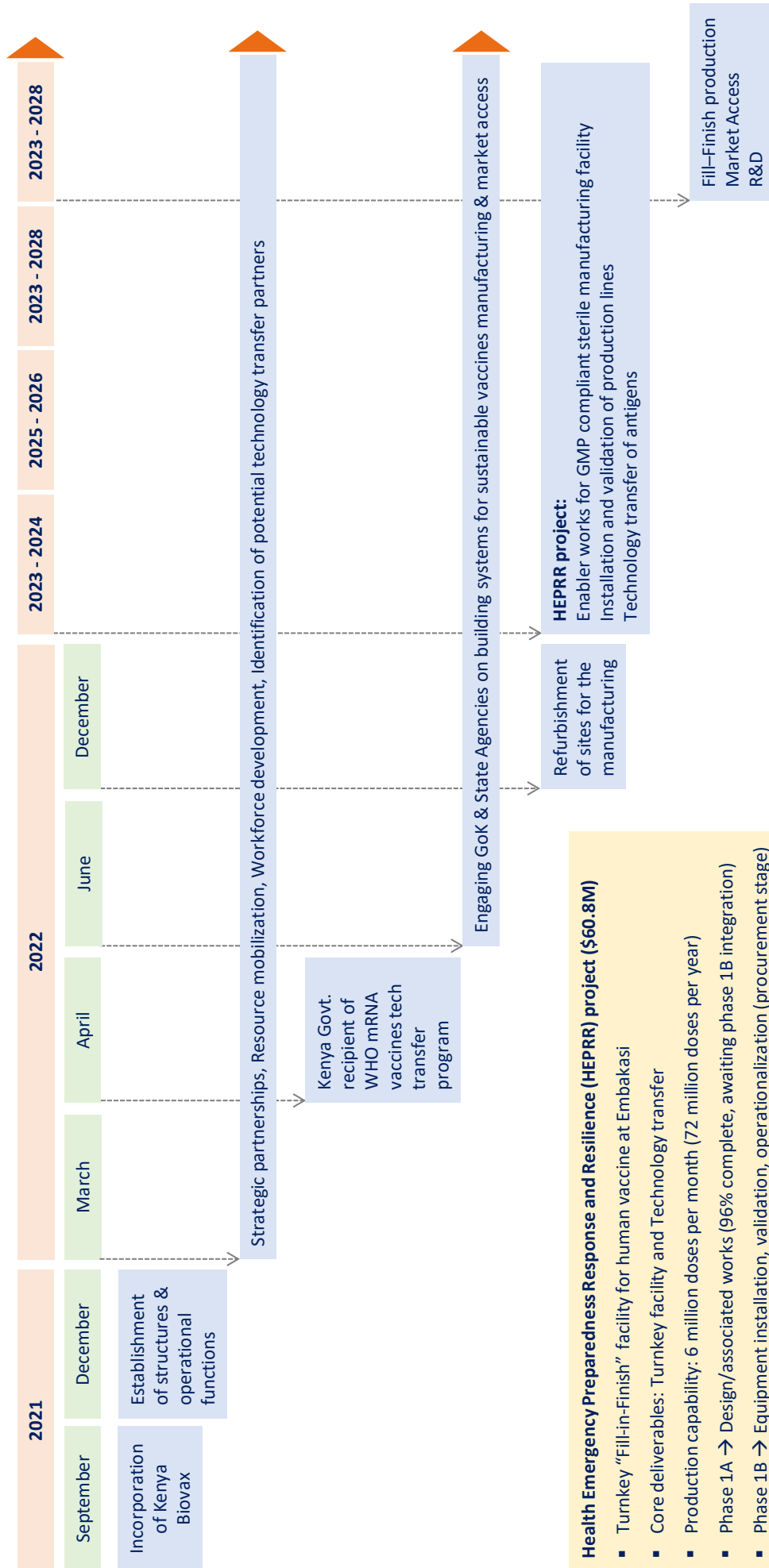


Figure 15: Kenya Biovax journey and evolution

Based on the extensive lifecycle for vaccine development, manufacturing, and commercialisation (Figure 14), private (risk-based) capital is unsustainable for financing such a project. As a result, concessionary financing remains the much-needed accelerator to get the ambitious local vaccines production agenda off the launch-pad:

- Government of Kenya and the World Bank have supported financing of Kenya Biovax initial setup projects (Figure 15), with US \$60.8M earmarked for HEPRR project to strengthen Vaccines PVC level 3 (Fill-Finish production) and Level 2 (Packaging and Labelling).
- Government of Kenya is partnering with Government of South Korea is supporting Kenya Biovax to establish an “End-to-End Smart Vaccines Production facility, with the feasibility study completed in 2024-2025. The project location is identified as Konza Technopolis, with PCV and TCV as the vaccine candidates and the projected cost.

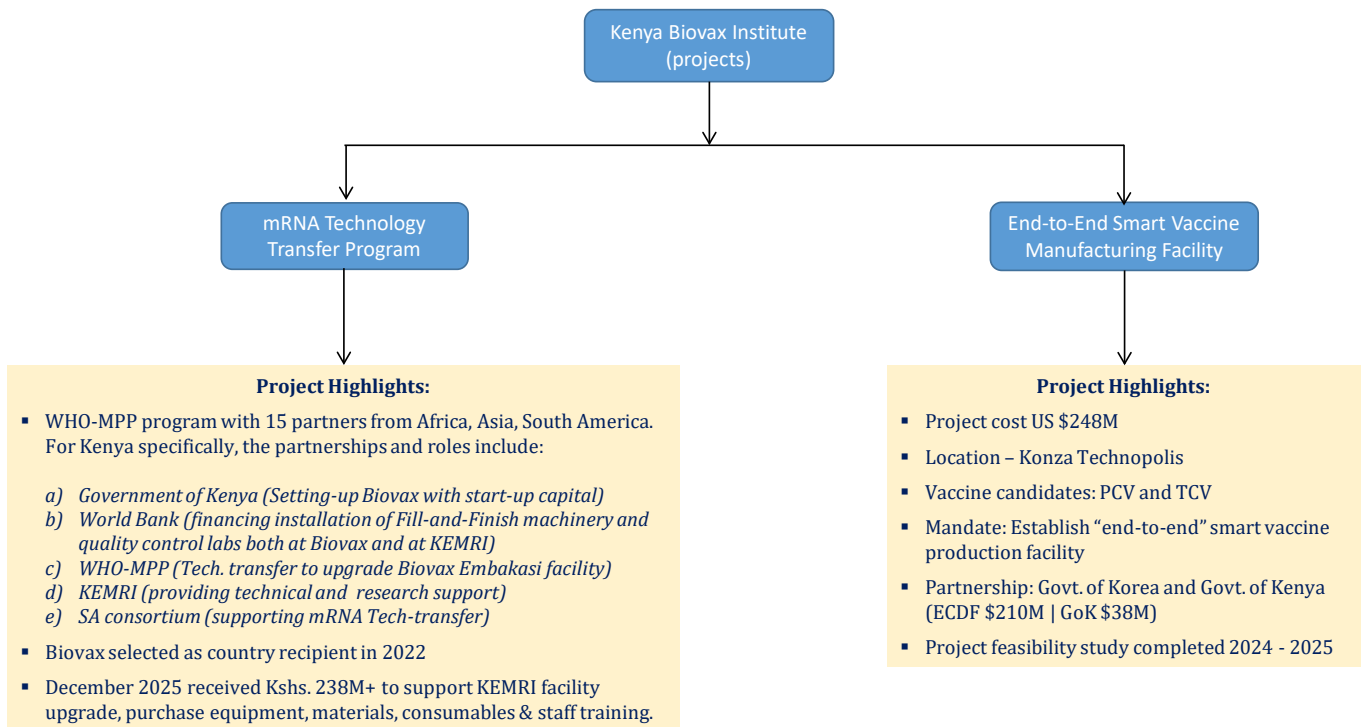


Figure 16: Kenya Biovax priority ongoing projects

2.2.4. Lifecycle for Diagnostics Product Development and Commercialization

Despite competitive regional and local markets, local manufacturers are constrained by limits to their ability and capability to obtain faster regulatory approvals, contain rising production costs and working capital challenges, secure lower competitive prices against cheaper imports (*despite*), and ensure long-term business sustainability. Figure 17 is a lifecycle map for RDT at a minimum of 1.5 years for the most fast-tracked registration-to-production process, and up to 2 years of working capital cycle. This is unsustainable in the context of private or risk-based financing and, for Kenya’s ambition to scale LM into PVC level 4 (API production) and level 5 (R&D), there is need for capital that is “*patient and forgiving*”, and an endowment financing for local manufacturing sustainability.

Lifecycle ecosystem map for products development and commercialization (e.g. diagnostics – RDT)

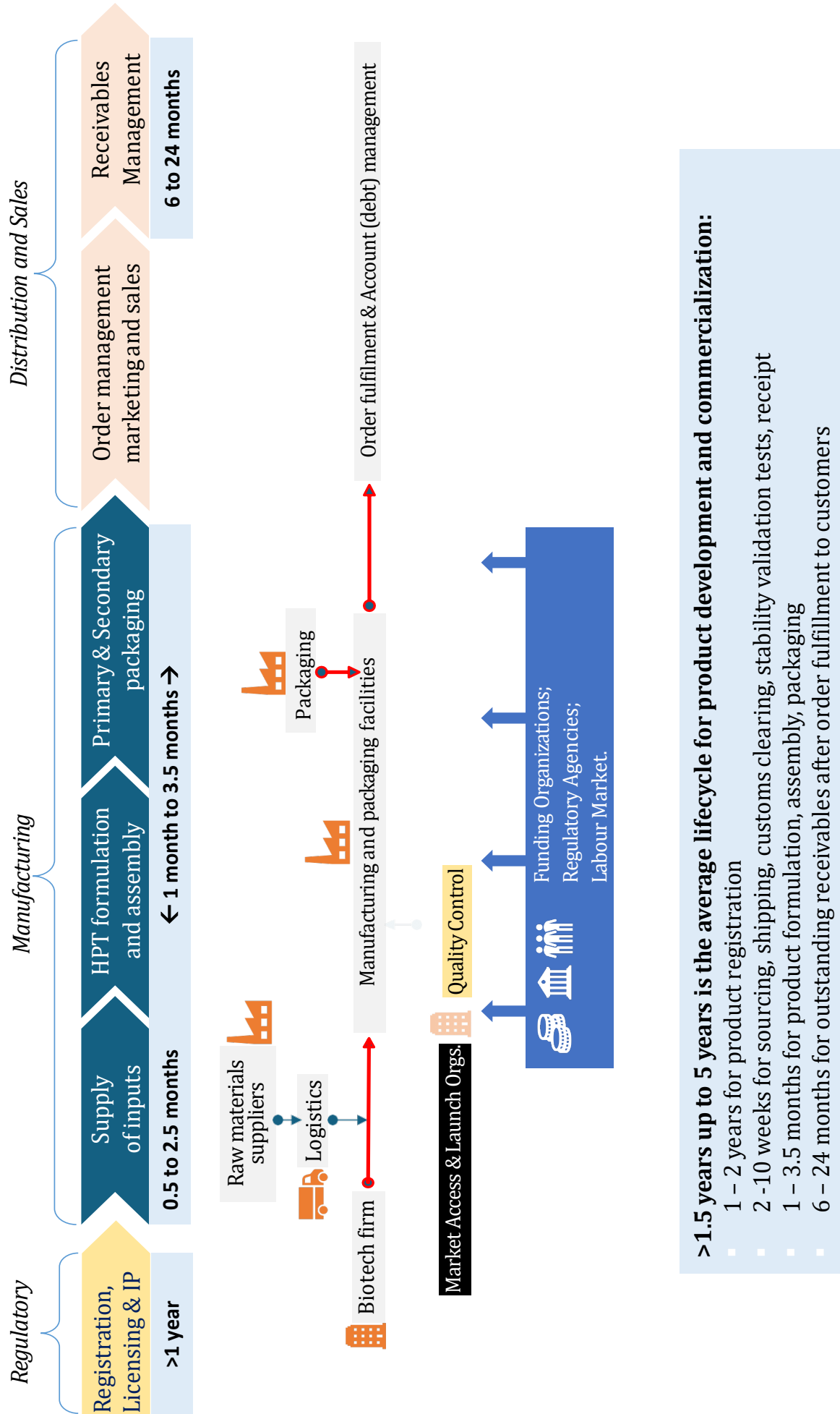


Figure 17: Average lifecycle for medical product development and commercialization in Kenya

In-depth analysis of HPT lifecycle ecosystem (regulatory, product development and commercialization) shows limited institutional workflow coordination around four (4) key ecosystem imperatives (i.e. Financing ecosystem, R&D ecosystem, Product development & regulatory ecosystem, and Supply chain and logistics ecosystem) which are enabler of LM progress if they are underpinned by a centrally coordinated governance and operating mechanism. Accelerated priority policy reforms are critical to shortening the regulatory cycles to help anchor health sector and LM as commercially viable for attractiveness to local HPT manufacturers (Figure 18).

All HPT regulatory, product development, and commercialization lifecycles for local manufacturer attractiveness

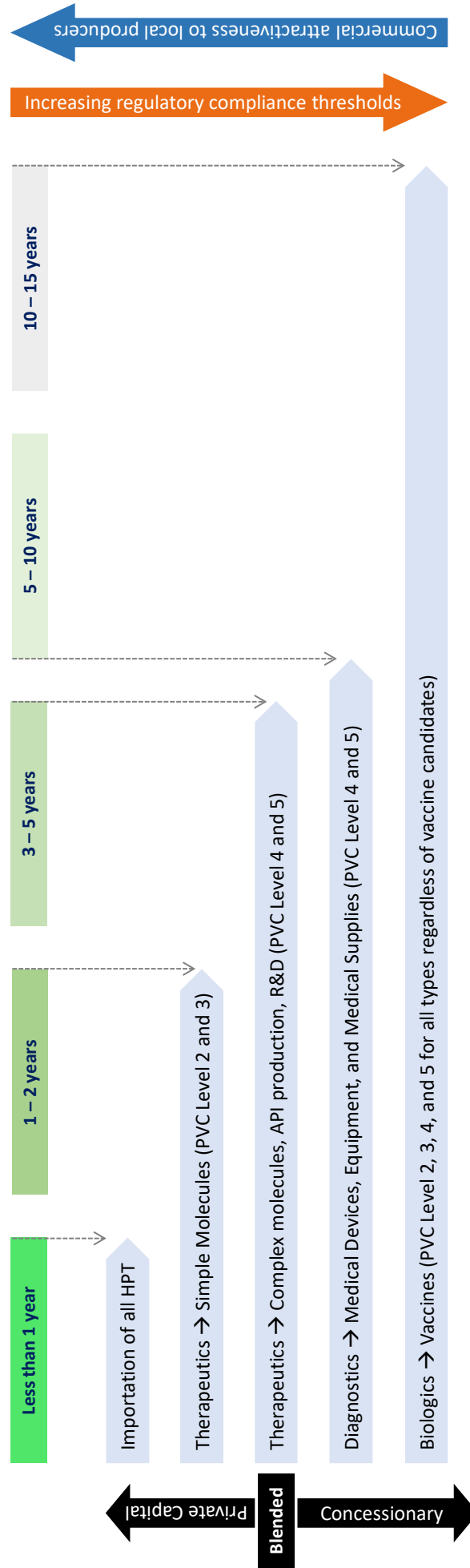


Figure 18: All HPT lifecycle (regulatory, product development, commercialization)

For instance, a local manufacturer accessing African market contends with US \$1,000 per product per country to register a medical device in each of 54 countries, with Kenya as the only country in the world with double registration bodies for devices (i.e. PPB and KEBS). Additionally, lack of operational Bioequivalence centre has resulted in KEMRI having mandate for validation-only and not validation and approval of devices. This compels a local manufacturer to part with US\$ 2,500 (Ksh. 300,000) and above for device testing, validation and approval in Europe. The multiplier effect of this operational capital flight would be best contained and retained within Kenya by investing approx. US\$ 10M – US\$ 15M to build a credible lab locally that meets stringent global standards.

2.2.5. Industry Skills and Capacity Development

Health Products and Technologies manufacturing is a highly technical operation, requiring a mix of qualified and skilled personnel to work in various functional areas namely research and development, formulation, production, regulatory affairs, quality control/assurance, engineering, supply chain logistics, and other support functions such as business development, human resource and finance. Additionally, specialised skills and know-how are required in areas including tooling and fabrication, clinical research, instrumentation and equipment calibration to name but a few.

Kenya is the manufacturing hub for pharmaceutical and biologics manufacturing in the region and has a workforce of over three thousand (3000) and growing personnel. Endowed with one of the most intellectually adept, progressive, and young population in Africa, the Government continues to invest in at least nine (9) universities and twenty (20) technical colleges that offer programs that feed into the industry including: pharmacy, engineering, microbiology, biochemistry, engineering and pharmaceutical technology.

However, technical and management technology mismatch between industry requirements and didactic training remain the largest challenge, thereby requiring significant investment in continuous skills upgrading. The absence of these skills results in a situation where local companies often incur additional and unavoidable costs for the maintenance of advanced technologies and equipment brought about by outsourcing to experts from out of the Continent.

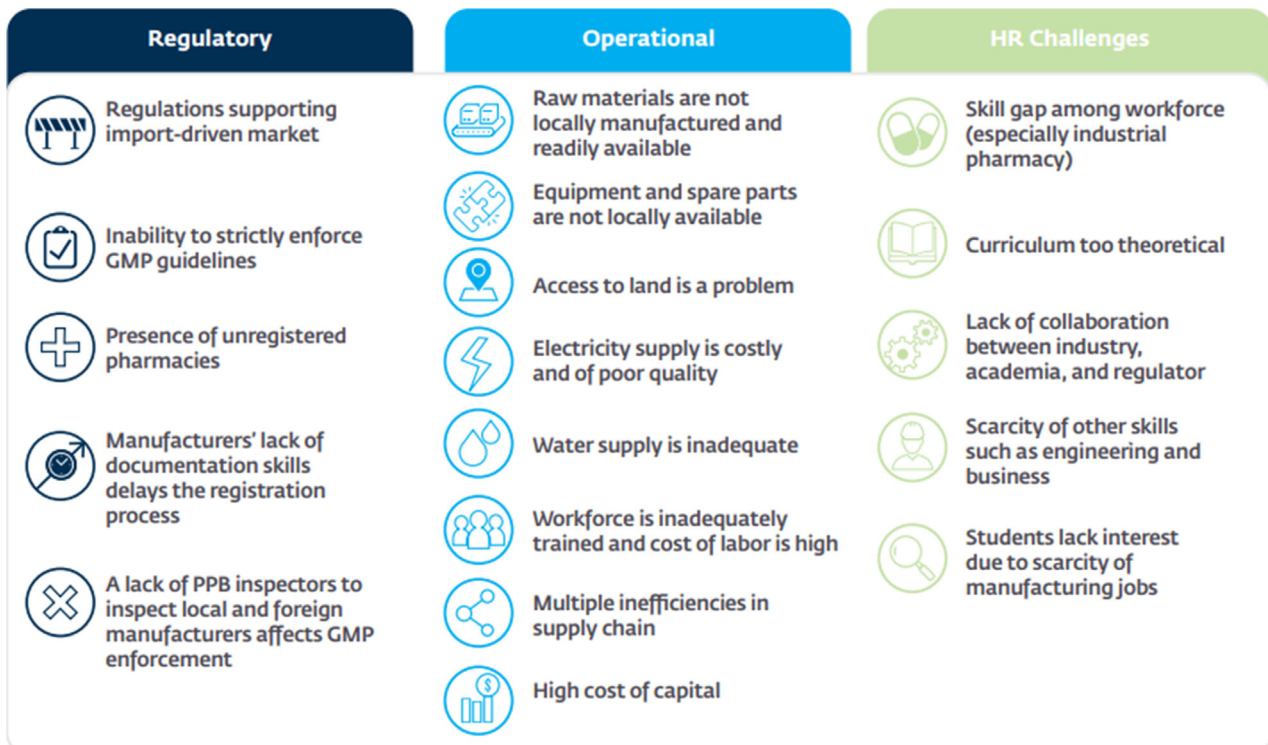


Figure 19: Summary of Challenges affecting Industry Players Source: Kenya Pharmaceutical Industry Diagnostic Report 2020 – Summary. IFC World Bank Group

A skills matrix analysis study conducted in sixteen manufacturing companies in 2019, found that there is adequate skills mix for current levels of production of essential medicines. However, there was a deficiency in research and development, specialised skills in pharmaceutical engineering, process engineering, validation and formulation scientists, HVAC and industrial Information Technology.

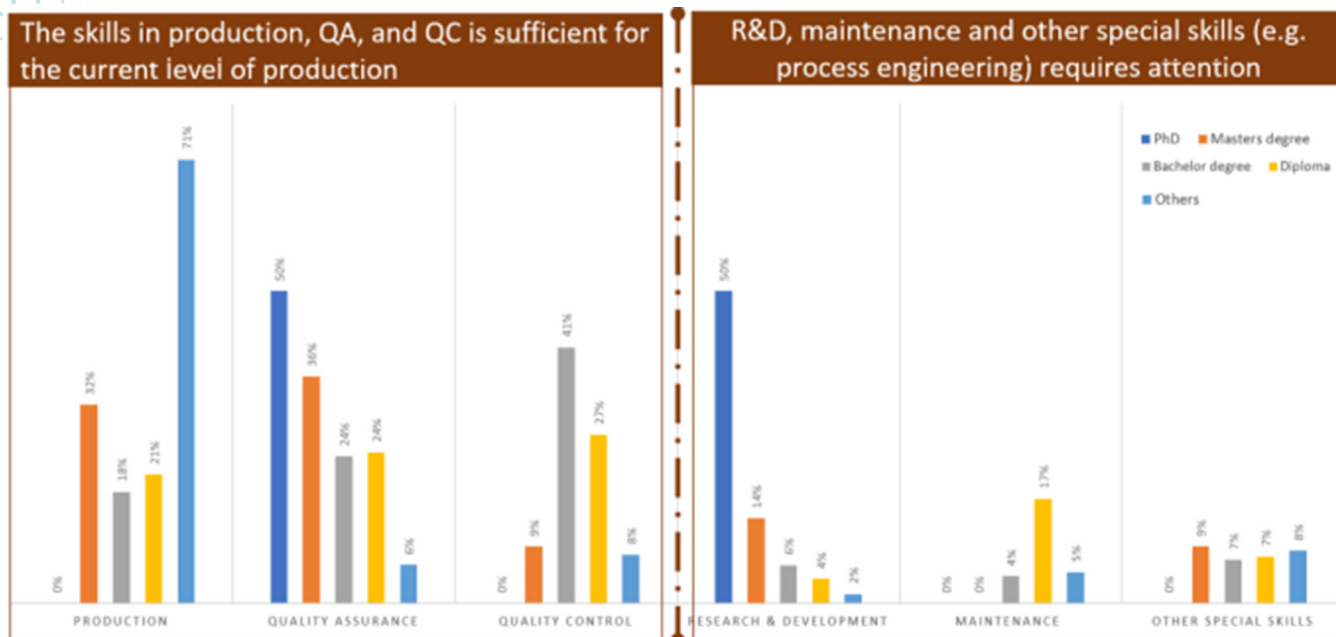


Figure 20: Skills Matrix Analysis: Skills Needs by Industry Source: Pharmaceutical Partnerships for Increased Access to Quality Essential Medicines in the East Africa Region Dec. 2019. The Scinnovent Centre

To address this, organisations such as the Africa CDC, World Health Organisation, the International Vaccine Institute, United States Pharmacopeia, among others, have developed competency frameworks and offer didactic and experiential courses and fellowships to bridge the knowledge gap and to serve as essential tools for ongoing training needs assessments and curricula development, while supporting industry to make better talent acquisition decisions.

Specifically, through the Africa CDC, there is a concerted continental effort to create collaborative networks of existing academic institutions and manufacturers to develop programs aimed at bridging the gap between academic knowledge and practical skills, thereby equipping the workforce with the expertise and skills development needed for the sector. This has led to the launch of the Regional Capability and Capacity Centres across the continent in 2023 focusing on talent development for manufacturing and research. By offering cross-training, the initiative, that Kenya is participating in, will ensure adaptability and versatility of the workforce and reinforce the sector’s resilience for health products and technologies manufacturing.

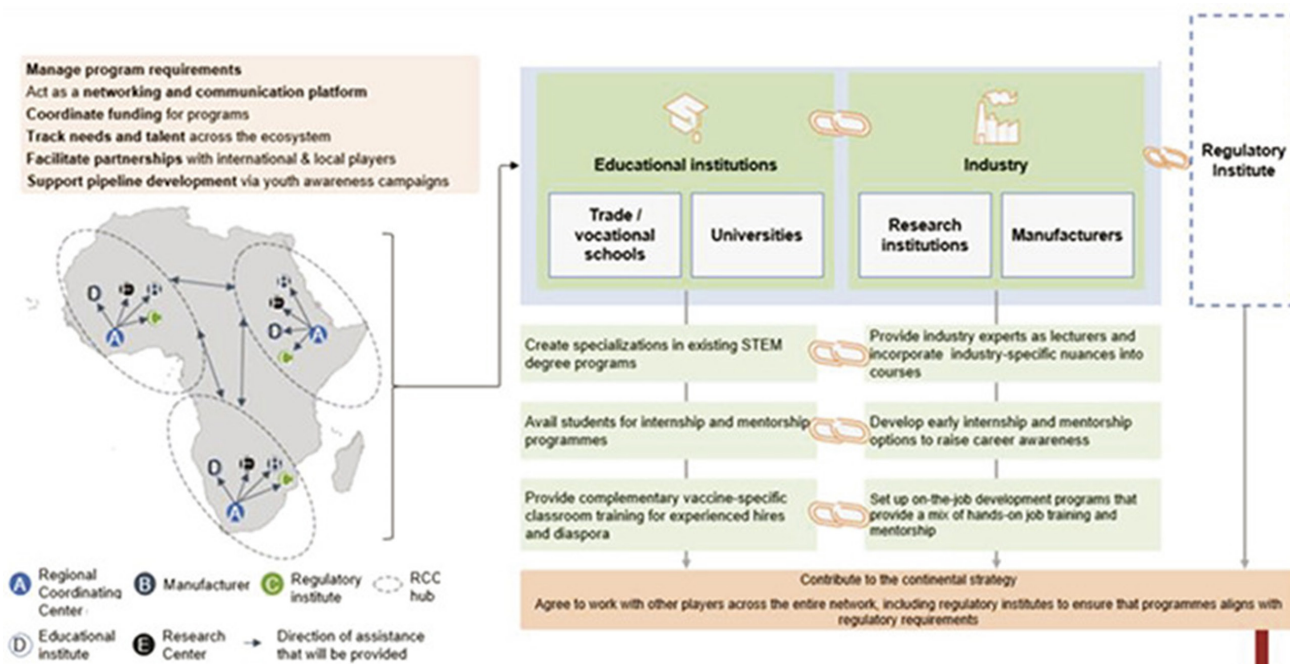


Figure 21: Concept Illustration by the Regional Capability and Capacity Centre Network (RCCN)

2.2.6. Competitive Regional Landscape Analysis

Pharmaceutical manufacturing industries of India, China, and Bangladesh have grown rapidly through bold policy reforms and global market positioning. India’s rise began with the 1970 Patents Act, which enabled its present world-leading generics sector, while China transformed after 1978 economic reforms, becoming the top global supplier of APIs.

Bangladesh leveraged the 1982 National Drug Policy and WTO TRIPS waivers to build a strong generics export base. In North Africa, Egypt (one of the continent’s oldest industries) remains a regional leader, while Morocco and Tunisia developed strong generics sectors from 1960s and 1980s respectively, with Morocco excelling in exports to Europe and West Africa.

In sub-Saharan Africa, South Africa hosts the most advanced industry, with significant research and vaccine production capacity; Ethiopia has a nascent but growing sector, supported by its 2015 Pharma Manufacturing Roadmap; Ghana maintains a modest generics industry supplying local and regional markets. Table 4 shows countries’ comparison across selected indicators.

Table 4: Comparison between Kenya and various countries across selected indicators

Indicator (2024)	Kenya	Bangladesh	China	Egypt	Ethiopia	Ghana	India	Morocco	South Africa	Tunisia
Population-million	53	172	1400	117	109	34	1500	38	63	12
GDP (US\$)	121B	452B	18T	407B	137B	21B	3.6T	157B	403B	49B
Av. Inflation rate (CPI) %	5.0	9.7	0.2	3.0	17.5	23.8	4.37	1.0	4.4	7.0
# of Local Manufacturers	28*	~300	>5000	~191	~14	~38	>3000	~40	~276	~40
Est. Local Manufacturing market size (US\$)	1B	3B	125B	5.9B	1.8B	433M	50B	2B	4.6B	2.2B
% of local demand met by Local Manufacturing	30%	98%	70%	93%	25%	30%	75%	65%	70%	60%

Source: World Bank, AfDB, IQVIA, National Government Statistics Bureaus, Regional Strategies, Artificial Intelligence (AI) generated & Trading Economics.

However, market shaping efforts to secure both local and regional markets still struggle with dual challenges of intractable imports and stringent export compliance.

As Table 5 below shows, only ~13% or 4 out of 30 HPT manufacturers in Kenya (3 pharma and 1 medical devices) established operations in EPZ, indicative of restrictive export market requirements and prohibitive compliance costs, despite the constraint of an intractable local public sector which the biggest sizeable and addressable yet not expandable HPT market due to poor payment. As such, upcoming initiatives like AfDB – Gates Foundation partnership on **Health Commodity Financing Plan** will help LMs to address local challenges as regional export market bottlenecks persist.

Additionally, concentration of manufacturing facilities (73%) around Nairobi and outside the EPZ’s and SEZ’s despite high labour rates compared to counties, may point to lack of industry-aligned and skilled pharmaceutical workforce or social amenities, and global compliance certifications to meet the stringent compliance requirements for the export market.

Table 5: Distribution of Local Manufacturing facilities versus EPZ and SEZ locations across Kenya

Category	SEZ Incentives	EPZ Incentives	General Incentives
Fiscal Incentives	<ul style="list-style-type: none"> 100% IDA (building, machinery) VAT zero-rated for local supplies Imports exempt from VAT, Excise/ Import Duties, and IDF 10% CT first 10 years 15% CT next 10 years 30% CT subsequently 0% WH income tax (management fees, royalty, interest paid to non-residents) while dividends paid to non-residents are tax exempt 	<ul style="list-style-type: none"> 100% IDA on new investment; Perpetually exempt stamp duty on legal instruments, Import duty on inputs, VAT; 10-year CT holiday 10-year WHT holiday 	<ul style="list-style-type: none"> 100% IDA on building and machinery from KSh 200M and above worth of investments Exemption of import duty on industrial machines (plus leather processing chemicals and equipment)

COUNTY	SEZ sites No.	SEZ sites Industry	EPZ sites No.	EPZ sites Industry	Local HPT Manufacturers # of firms	Local HPT Manufacturers # in EPZ or SEZ
Homa Bay	1	Agribusiness				
Kajiado	1	Technology				
Kiambu	7	1-FMCG, 3-Agric, 4-Varied			1	--
Kilifi	1	Logistics	2	Varied, Apparel, and Health	2	1 (EPZ)
Kirinyaga	1	Agribusiness	1	Agribusiness		
Kwale	2	Varied	1	Varied		
Lamu	1	Tourism				
Machakos	3	1-Real estate, 2-Agribusiness	1	Varied, Health	4	3 (EPZ)
Mombasa	6	3-Varied, 3-Logistics	4	Varied, Apparel and Logistics		
Nairobi	4	1-Varied, 1-Agribusiness, 1-Logistics, 1-Transport.			22	--
Nakuru	3	1-Varied, 1-Agribusiness, and 1-Logistics			1	--
Nyandarua	1	Tourism				
Trans Nzoia	1	Agribusiness				
Uasin Gishu	2	1-Varied, 1-Apparels				
Voi	--	--	1	Varied		
TOTAL	34		10		30	4

Table 5 should trigger a re-thinking of incentives on location preferences by local manufacturers, to attract climate-smart and sustainable investments that promote and preserve the quality of key determinants of population health and well-being (*i.e. air, water, and soil*) while also helping Kenya to attain its health-sector obligations in green procurement, green manufacturing and green supply chain as per the NDC commitments in the Paris Agreement. As it stands, 73% (or 22 of the 30) local manufacturing facilities are situated in Nairobi which is already struggling with high cost of living, infrastructure constraints, congestion, pollution, amidst concerted efforts to restore green living spaces and secure population well-being.

Consideration should be made of Annex 9.2 which provides country case-studies with useful value propositions for successful local manufacturing approaches, quick-wins, and lessons that can help Kenya in addressing systemic gaps. Lessons from these case studies are summarised in Table 6:

Table 6: Summary of benchmark country case-studies on LM value propositions and approaches

Case-study prioritized by quick-wins and lessons	H	M	L	Relevance
1. Nigeria (PVACor Presidential Initiative to Unlock Health Value Chain) <ul style="list-style-type: none"> Fiscal and non-fiscal incentives (through Executive Order) Address significant issues in health sector (under-investment, poor policy implementation, regulatory challenges, services, and infrastructure) Strengthen industry to create more accessible and affordable HPT & quality jobs 	✓			High
2. South Africa (Government-led local Biotech talent) <ul style="list-style-type: none"> Progressed R&D, Clinical Trials, and other biotech activities Ongoing shortfall in practical and regulatory skills to advance industry Encountered lack of holistic approach to developing vaccine strategy and talent at all skills and structural levels 	✓			High
3. Ghana (Cost effective strengthening of local pharma industry) <ul style="list-style-type: none"> Enabling environment for sustainable development of local pharma industry Innovation & tech transfer via South-South cooperation & collaborative efforts Sectoral support via regional harmonization of regulations at all levels of WAHO 	✓	✓	✓	Medium
4. South Africa (Biovac technology transfer – PPP model) <ul style="list-style-type: none"> Local supplier guarantees vaccines flow to reduce shortage Manufacturer leverages financing, reduced risk and regulatory support Improved vaccines potency and supply security for citizenry 	✓			High
5. Bangladesh (Turning the tide in 5 years) <ul style="list-style-type: none"> 75% reduction of import that address national pharmaceutical needs Developed >98% local manufacturing capability 		✓	✓	Medium
6. India (Production-linked Incentive or PLI schemes) <ul style="list-style-type: none"> PLI scheme differentiated as accelerator from other traditional govt. subsidies Accelerated growth of 14 domestic industries (incl. Local Pharma manufacturing) and enhanced their competitiveness in the global market 	✓		✓	Medium

⁸Overall, when scored on country attractiveness for regional manufacturing hub based on industry parameters in Table 7 below, Kenya did not outcompete benchmark countries. As such, concerted cross-sectoral efforts are required to overcome systemic and endemic challenges and improve the landscape and climate for anchoring Kenya’s local manufacturing initiative as a regional hub and attracting investments, while also riding on the political goodwill through the AU championship for Local Manufacturing of HPTs.

⁸ https://www.globalpetrolprices.com/electricity_prices/

Table 7: Country attractiveness as Regional Manufacturing Hub

Countries	World Bank (2024)		National Regulatory Authority		Bioequivalence (BE) Centre or Clinical Research Organization		Pharmacists per 10,000 population	Value proposition for accelerating policy action	Electricity Price for Businesses (averages across 2023 to 2026) USD per kWh	Competitiveness
	Income level	ML status	Scope of Products	Product Development potential	LM attractiveness					
Kenya	LMIC	ML-2	unavailable	One (1) aspirational	0.45	Govt.-backed mRNA technology transfer	0.175	Low-Moderate		
Ethiopia	unclassified	ML-3	1. Medicines 2. Vaccines (non-producing)	One evidence of past studies only	1.60		0.018	Low-Moderate		
Tanzania	LMIC	ML-3	1. Medicines 2. Vaccines (non-producing)	Two evidence of past studies one	0.55		0.093	Low-Moderate		
Rwanda	LIC	ML-3	1. Medicines 2. Vaccines (non-producing)	One (1) aspirational	0.05	Govt.-backed mRNA BioNTainer	0.077	Moderate		
Uganda	LIC	ML-2	unavailable	unavailable	0.35	Govt.-led biotech talent 2001; and Biovac PPP tech. transfer 2003	0.117	Low		
South Africa	UMIC	ML-3	1. Vaccines (producing)	Two operational	2.85		0.103	Moderate -- High		
Zimbabwe	LMIC	ML-3	1. Medicines 2. Vaccines (non-producing)	One (1) aspirational	1.25		unavailable	Low		
Botswana	UMIC	ML-2	unavailable	unavailable	0.55	Presidential Initiative to Unlock the Value chain (PVAC 2024)	0.12	Low		
Nigeria	LMIC	ML-3	1. Medicines 2. Vaccines (non-producing)	One (1) aspirational	1.45		0.05	Moderate -- High		
Ghana	LMIC	ML-3	1. Medicines 2. Vaccines (non-producing)	One (1) aspirational	2.10	Cost effective strengthening	0.134	Moderate		
Senegal	LMIC	ML-3	1. Medicines 2. Vaccines (non-producing)	One (1) aspirational	0.25		unavailable	Moderate		
Egypt	LMIC	ML-3	1. Vaccines (producing) 2. Medicines	One (1) operational	5.50		0.037	High		
Morocco	LMIC	ML-2	unavailable	One (1) operational	0.32		0.11	Moderate		
Tunisia	LMIC	ML-2	unavailable	One (1) operational	2.50		0.115	Moderate		
Bangladesh	LMIC	ML-2	unavailable	One (1) operational	1.20	Turning the tide 2010 - 2015	0.1	Moderate		
Pakistan	LMIC	ML-2	unavailable	Four (4) operational	2.40		0.154	Moderate		
China	UMIC	ML-3	1. Vaccines (producing)	Six (6) operational	4.00	State-backed API industry	0.098	High		
India	LMIC	ML-3	1. Vaccines (producing)	Eight (8) operational	12.50	PLI incentives scheme 2020	0.123	High		

2.2.7. Stakeholder Analysis

Stakeholder mapping was done to understand their interests and concerns towards a successful formulation and implementation of local HPT manufacturing strategy.

Table 8: Stakeholders mapping and analysis

Stakeholder category	What the LM strategy expects from the stakeholder	What the stakeholders expect from actors within LM strategy
Users or Citizens	<ul style="list-style-type: none"> Purchase of locally produced HPT. Active participatory feedback on locally produced HPT. 	<ul style="list-style-type: none"> Quality, safe, efficacious and affordable HPT. Access to diverse HPT as per demand trends.
Public and Private Health Providers	<ul style="list-style-type: none"> Prioritize purchase of locally produced HPT. Feedback on locally produced HPT. 	<ul style="list-style-type: none"> Availability of quality, safe, efficacious and affordable HPT. Access to diverse HPT as per demand trends. Adequate and timely financing to facilitate purchase of HPT.
County Governments	<ul style="list-style-type: none"> Prioritize purchase of locally produced HPT. Feedback on locally produced HPT. Timely payments to HPT manufacturers. 	<ul style="list-style-type: none"> Availability of quality, safe, efficacious and affordable HPT. Access to diverse HPT as per demand trends. Adequate and timely financing to facilitate purchase of HPT. Adherence to relevant county laws.
Kenya Revenue Authority (KRA)	<ul style="list-style-type: none"> Promoting compliance with tax regulations. Diversify approaches to meet revenue targets. 	<ul style="list-style-type: none"> Adherence to revenue collection procedures.
The National Treasury and Economic Planning	<ul style="list-style-type: none"> Consider tailored tax incentives and other schemes that can spur local manufacturing of HPT. Economic stability and growth. Public Finance Management. Development planning. Create policies for a favourable manufacturing environment e.g. taxes, levies, duties, EPZs/SEZs, etc. 	<ul style="list-style-type: none"> Adherence to responsible manufacturing practices aligned to policies. Support the economic stability and growth agenda of the government.
Pharmacy and Poisons Board (PPB)	<ul style="list-style-type: none"> Achieve World Health Organization (WHO) Maturity Level 3 categorization against the Global Benchmarking Toolkits. Timely registration of local manufacturers' products. Strengthen National Regulatory System e.g. GMP compliance. Refine and improve the inspection process. Regularly train local manufacturers in selected critical areas. Address overlapping or conflicting mandates with other regulators in some product areas. 	<ul style="list-style-type: none"> Local manufacturers to comply with GMP and other sector regulatory requirements.

Stakeholder category	What the LM strategy expects from the stakeholder	What the stakeholders expect from actors within LM strategy
<p>Ministry of Energy, Energy and Petroleum Regulatory Authority (EPRA) and other allied agencies.</p>	<ul style="list-style-type: none"> • Economic efficiency • Energy efficiency, reliability, stability, cost and power quality • Consumer protection • Environmental protection • Provide competitive energy pricing and tariffs. • Ensure supportive energy planning. 	<ul style="list-style-type: none"> • Prompt settlement of energy bills. • Local manufacturers to actively engage the Ministry and EPRA.
<p>Ministry of Industry Trade and Investments (State departments including Kenya Exports Promotion and Branding Agency).</p>	<ul style="list-style-type: none"> • Promoting domestic and foreign investment in Kenya. • Enhance trade and the ease of doing business. • Drive initiatives like “Buy Kenya- Build Kenya”. • Develop, diversify and brand Kenya’s market and exports. • Allay local HPT quality misconceptions 	<ul style="list-style-type: none"> • Engage and collaborate for effective coordination of investments promotion. • Provide relevant data. • Take up EPZ/SEZs offers. • Engagement for the implementation of international treaties. • Diversify products for the exports market. • Observe good quality standards. • Support in favourable national branding.
<p>Kenya Medical Supplies Authority (KEMSA).</p>	<ul style="list-style-type: none"> • Procurement, warehousing and distribution of essential HPT. • Establishment of a network of storage, packaging and distribution facilities. • Supporting county governments to establish and maintain appropriate supply chain systems for essential medicines and medical supplies. • Supporting local manufacturing through preferential procurement of locally manufactured essential HPT. • Prompt payments to avoid stock-outs and reduce costs. 	<ul style="list-style-type: none"> • Increased local manufacturing of essential HPT. • Supply of HPT that meets established quality standards.
<p>Academia (universities and other relevant training institutions)</p>	<ul style="list-style-type: none"> • Produce competent professionals relevant to the HPT manufacturing sector. • Updated curricula in line with industry and technology requirements. • Collaboration with local HPT manufacturing industries. • Research and development for enhanced quality in HPT development and manufacturing processes. • Technology transfers and innovation for commercialization. 	<ul style="list-style-type: none"> • Collaboration with industry to ensure appropriate integration of concepts across courses and connection between theory and practical application. • Strong linkages between academia and local HPT manufacturers.

Stakeholder category	What the LM strategy expects from the stakeholder	What the stakeholders expect from actors within LM strategy
Kenya Bureau of Standards (KEBS)	<ul style="list-style-type: none"> Promote industry and trade through standardization, testing, conformity assessment, quality awareness and recognition. 	<ul style="list-style-type: none"> Conformity with quality standards. Collaboration with sector players to address bottlenecks that may hinder the growth of local manufacturing.
Kenya Medical Research Institute (KEMRI)	<ul style="list-style-type: none"> Technology mining and commercialization of intellectual properties. 	<ul style="list-style-type: none"> Collaboration to increase research, development, innovation and commercialization for the local manufacturing industry.
Kenya Biovax Institute (KBI)	<ul style="list-style-type: none"> Provide incubation and pilot production facilities e.g. current discussion on mRNA technology, diagnostics and medical devices innovation, vaccine and biotherapeutic research and development, capacity building and human resource development. 	
Referral Hospitals	<ul style="list-style-type: none"> Timely and high-quality radiopharmaceutical availability. Primary diagnosis and management of cancer patients. Expansion into theragnostics (both therapeutic and diagnostic approach) -Kenyatta University Teaching, Research and Referral Hospital (KUTRRH). 	<ul style="list-style-type: none"> About radiopharmaceutical and related products: Develop strategies, guidelines, and standards. Collaborate with the MoH-DHPT, PPB, and International Atomic Energy Agency (IAEA) and other stakeholders to develop national guidelines. Develop a robust quality assurance and regulatory compliance framework for radiopharmaceuticals. Improve logistics for radioisotopes and other products used in theragnostics due to their short lifespan. Enhance affordability of medicines.
Industry Associations	<ul style="list-style-type: none"> Increased production of essential HPT. Affordable cost of HPT (priced products). 	<ul style="list-style-type: none"> Improved access to financing. Protection from unfair competition from importers. Improved perception and uptake by Kenyan consumers on locally manufactured products. Concessions, levies and tax incentives e.g. allowance for input VAT claims on capital expenditure, acquisition of laboratory equipment, etc. Reduced cost of doing business e.g. maintenance, rent, and electricity. Improved turnaround time for approval of new HPT. Improved quality of packaging materials. Imports' substitute initiatives

Stakeholder category	What the LM strategy expects from the stakeholder	What the stakeholders expect from actors within LM strategy
Wholesalers and distributors	<ul style="list-style-type: none"> Affordable HPT. Conducive business environment. 	<ul style="list-style-type: none"> Affordable HPT. Conducive business environment i.e. supportive policies, laws and regulations.
Implementing partners e.g. Clinton Health Access Initiative (CHAI), PATH, UNITAID, and World Health Organization (WHO), AMREF, and Oxygen Alliance,	<ul style="list-style-type: none"> Supporting initiatives for enhanced local manufacturing. Supporting resilient supply chains for HPT and special program products. Supporting affordability and quality HPT especially for HIV, malaria, HCV, TB, postpartum hemorrhage (PPH) and rapid diagnostic test kits. 	<ul style="list-style-type: none"> Partnerships with the government to ensure sustainability. Prudent resources allocation and utilization by public and private sector players in local manufacturers.
Professional associations e.g. Pharmaceutical Society of Kenya and Kenya Pharmaceutical Association (KPA).	<ul style="list-style-type: none"> Promoting the professional interest of members. 	<ul style="list-style-type: none"> Employment and capacity building of professionals by local manufacturers.
Regional Economic Communities (RECs): EAC, IGAD, COMESA, and AfCFTA.	<ul style="list-style-type: none"> Promote harmonization of HPT laws and regulations. Promote regional common markets. 	<ul style="list-style-type: none"> Local manufacturers engage and take up opportunities within regional blocs. Local manufacturers producing priority HPT for the regional market.

2.3 SWOT Analysis

Kenya’s local HPT manufacturing industry was analysed using the SWOT framework, with desk-reviews and stakeholders’ feedback as key approaches for this analysis.

Table 9: SWOT Analysis of LM (Strengths, Weaknesses, Opportunities and Threats)

Strengths	Weaknesses
<ul style="list-style-type: none"> • Political goodwill, commitment, and institutional LM anchoring: <i>Presidential Local manufacturing championship at AU level</i> <i>Alignment with Vision 2030, BETA, UHC, Health Act, KNPP</i> <i>Diverse institutional stakeholders (academia, private, partners)</i> <i>347 products on the Preferential Procurement Master Roll</i> <i>MOH and MITI co-leadership for coordination</i> • Most advanced LM industry anchored to regional integration markets with low-scale competitors (37 of 55 EAC facilities). • Workforces’ availability for PVC levels 1, 2, and 3 • High untapped HPT market potential locally and regionally (addressable but not fully accessible, and serviceable) • Operationalization of Kenya Biovax Institute. • Sectoral policy support (Vision 2030, UHC, Health Act, KNPP, non-fiscal incentives). • Infrastructure capability (regional hub, sea/airports, rail, roads) • Increasing investments in HPT manufacturing. • Improved coordination and collaboration mechanisms with stakeholders at the MOH. • Developed distribution infrastructure network (ports, road, rail) 	<ul style="list-style-type: none"> • Lack of financial advisory capacity in health to address inter-agency workflow dysfunction derailing product development and commercialization lifecycle; Mismatched value-chain unit economics; Lack of robust due-diligence and HPT value pool risk profiles for credible investment cases to navigate complex dynamics of family businesses accounting for 80% local production capacity. • LM governance design misaligned with operational architecture, not reflecting political goodwill (e.g. embracing other country’s best practices without matching investor-friendly LM policies) • Weak enforcement goodwill in PSM policy and legislative framework to protect local manufacturers. • Lack of transparency in regulatory pathway for ML-3 status (PPB), GMP and PQ (Manufacturers). • No BE framework to support LM and BE data to restore public confidence in quality, safety & efficacy. • Uncoordinated science-policy-market continuum to harness policy research for commercialization. • Constraining fiscal and non-fiscal incentives, infrastructure, resources and technical knowledge. • Lack of institutional capacity and resources in R&D, bioequivalence (BE) center, CROs, and product development. • Regulatory hurdles, duplicity, and bureaucracy in the formative setup for new HPT manufacturing • Lack of industry-aligned skilled workforce for PVC levels 4 and 5 (skills, training, market or industry). • Limited and inadequate market shaping efforts and deployment of market-shaping tools. • Infrastructure, knowledge and technology to meet the needs of PVC level 4 (API) and level 5 (R&D) • Public sector payment delays an Inadequate government funding to support R&D or API technology transfer. • Inability to harness research outputs for both decision making and commercialization. • Limited support for SMEs growth and expansion into innovation and capital access • API import sourcing and supply chain logistics challenges hindering HPT availability and access. • Limited R&D in local market (unable to scale up PVC levels 5 and 4) • Lack of dedicated funding pool to incentivize LM projects • Stakeholders’ coordination and collaboration challenges.

Opportunities	Threats
<ul style="list-style-type: none"> Partner-led regional accelerators for anchoring Kenya’s LM: <p>WHO mRNA: Kenya recipient of Vaccine Technology Transfer</p> <p>EAPOA: East Africa Program on Oxygen Access by UNITAID and MedAccess, prioritized Kenya (2024 – ongoing in Kilifi)</p> <p>RMEA: UNITAID’s Regional Manufacturing for Equitable Access (2025–2029) prioritize Kenya for therapeutics (anti-malarial, HIV treatments, PPH medicines) and rapid diagnostic tests for HIV, malaria, other priority diseases.</p> <p>AIM: African Initiative for Medical Access and Manufacturing 2030 by World Bank prioritize Kenya and 8 other countries for infrastructure, financing and partnerships.</p> <ul style="list-style-type: none"> Underutilized installed LM capacity at ~60% average annual capacity utilization of manufacturing facilities, 80% production capacity contributed by 10 LMs); FDF (final dosage form) value chain (fill & finish) at 30% in value produced locally. Leverage existing family businesses as catalysts for introducing tailored innovative financing solutions and technology transfer for long-term scalability and sustainability in HPT sector Export financing, credit insurance, partner-accelerated market-oriented investments, green financing for environmentally sustainable practices to scale local/ regional access & demand. Unexploited local and regional market with potential to expand into niche production areas e.g. radio and nuclear medicines, biologics, liposomes. Value addition in manufacturing (syndicating APIs) and finished products, new technological innovations e.g. AI and robotics. Investment and market-shaping in adjunct industries e.g. packaging, printing, glass manufacturing; Traditional and alternative medicine (TAM) practices in Kenya. 	<ul style="list-style-type: none"> Unsustainable business model with lengthy/dysfunctional product development lifecycle ecosystem, poor working capital conversion cycle with public sector customers, and difficulty producing high volumes for economies of scale in unit costs and ex-works pricing. Regulatory barriers lack greater harmonization and acceleration e.g. Kenya Drugs Authority Bill 2024 delayed; Long-winded regional harmonization to operationalize African Medicines Agency (AMA); Slow harmonization of cross-border trade (agreements) to access regional African markets; Existing regulatory options not “fit-for-purpose” (no WHO-PQ eligible RDT marker, no tFDA ARV marker) Limited access to risk-free capital to upgrade production capability for tech. transfer partnerships. Competition against imports in local market and high compliance restrictions in export markets Manufacturers capability and financial limitation to get certification, approvals, and lower prices Importation of almost all APIs (>95%) required in the country (global supply security risks) >80% of local manufacturers produce similar portfolios of generics (saturation & diversification risk) Difficulties building industrial professional workforce for securing or executing technology transfer. High production costs (utilities, labor, energy); High import costs and supplier diversity challenges (e.g. antigens); High customs duties and tariffs for both imports and exports (e.g. RDL, Excise duty). Substandard/ falsified/counterfeit/poor-quality HPTs vis-a-vis PPB supervisory capacity constraint. Fragmented data sources and systems affecting regulatory, policy and market coordination goals. Fragmented regional markets eroding economies of scale (could benefit from strategic collaboration within Trade and Promotion campaigns for amalgamation through regional integration (e.g. AfCFTA) Geopolitics impacting high import dependency variables (oil supply, forex, cost of business and raw material (API) imports amidst local HPT manufactures’ competition with cheap imports. Training and retaining HR in LM (risk of migration of skilled workers to other countries). Regional gatekeeping hindering free trade and movement of products; Limited political support for countries willing to procure from neighbors (hubs); Slow rollout of Africa Free Trade Agreement The growing push for sustainability and stricter environmental compliance regulations

2.4 PESTEL Analysis

To deepen the broader contextual understanding of the national environment, an analysis of the political, economic, socio-cultural, technological, environmental and legal/regulatory (PESTEL) environment and their strategic implications on local manufacturing was conducted through desk-review and feedback from stakeholders. Table 4 shows the analysis of the PESTEL factors.

Table 10: PESTEL Analysis

Political factors
Government policies: Kenya government has prioritized healthcare access under UHC, advancing policies such as “Buy Kenya-Build Kenya” to encourage locally manufactured products. Vision 2030 espouses policies aimed at infrastructure development and industrialization to support the sector.
Political goodwill - Government has undertaken business-friendly reforms to streamline licensing, reduce bureaucratic red tape, and enhance investor confidence. Kenya’s President is the current African Union champion for local manufacturing.
Trade Agreements and Regional Integration - Kenya is a member of the East African Community (EAC) and the African Continental Free Trade Area (AfCFTA), Africa CDC, AMA and COMESA which provide manufacturers access to a broader regional and continental market.
Regulations - Pharmacy and Poisons Board (PPB), Kenya Bureau of Standards (KEBS), and Ministry of Health (MOH) regulate production, distribution, sale, marketing and quality assurance for HPT.
Public-Private Partnerships (PPPs) remain a major opportunity for Government to partner with private sector players to invest in and improve local HPT manufacturing.
Economic factors
Government incentives and taxation: Government offers various incentives for manufacturers, such as tax exemptions for capital goods, but implementation of the tax policies continues to be challenges e.g. inability of manufacturers to claim VAT on certain inputs due to their classification as VAT exempt, bureaucratic delays and unfavourable taxes considering exported HPT.
Infrastructure development: Government investments in infrastructure, including roads, railways, and energy supply, are essential for boosting manufacturing efficiency
Funding allocation for research projects - Research and Development (R&D): Investment in R&D can foster innovation and the development of new products, improving the manufacturing sector’s ability to compete in both local and international markets.
Inflation: impacts on the cost of imports and consumer demand for manufactured goods
High costs of doing business amid inadequate funding for local HPT manufacturers and volatile tax regime leading to challenging operating environment including collapse and closure of businesses.
Access to finance: The availability of loans from local banks to support investments.
Special Economic Zones for Export Promotion: SEZs incentivizes local manufacturers to export
Social factors
Large youthful population: The availability of a young and increasingly educated workforce offers competitive advantages.
Significant population remain unreached with life-saving HPT in rural and marginalized areas.
Population growth and sporadic informal settlement urbanization: lead to higher demand for healthcare services and HPT.
Mismatch between workforce skills, training and market demands for industry growth
Perception of local products: Kenyans consider local manufactured commodities to be inferior.
Unethical practices in the sector e.g., compromising on quality, substandard and falsified HPT
Social responsibility and sustainability: Growing awareness of environmental and social issues is pushing manufacturers to adopt more sustainable and socially responsible practices, including ethical sourcing, fair labour practices, and reducing environmental footprints

Technological factors
Some local manufacturers do not have adequate modern physical infrastructure and technology, for example, specialized storage and requirements i.e. cold chain.
Technology in complex manufacturing processes e.g. Artificial intelligence (AI), machine learning and other evolving technologies
Digital transformation: Rise of e-commerce and digital marketing is expanding opportunities for manufacturers to sell locally and globally. Social media is an essential platform for communication, advocacy, and activism, influencing choices among consumers (e.g. buyer beware, telemedicine)
Environmental factors
Climate change impact - disruptions in supply chains due to extreme weather conditions (floods and droughts) affect logistics for raw materials, finished goods, and cold-chain products.
Sustainability, green production and recycling: Increasingly stringent environmental regulations around waste management, carbon emissions, and pollution control are pushing manufacturers to adopt cleaner, more sustainable production methods. There is an increasing push for recycling and circular economy practices in manufacturing to minimize waste and enhance resource efficiency.
Natural resources: Endowed with vast natural resources to be leveraged for local manufacturing. However, over-exploitation or mismanagement of these resources pose long-term challenges.
Legal and Regulatory factors
Intellectual property protection and commercialization: - Enforcement of the IP laws can encourage innovation and protect local manufacturers' inventions and trademarks from counterfeiting and intellectual theft and further encourage the commercialization of patents.
NEMA Act: Compliance with environmental, health and safety regulations/requirements comes with additional costs for manufacturers e.g. procurement of incinerators or hiring of incineration services and workplace safety measures.
Procurement laws: Public sector procurement processes are governed by the PPADA 2015, under which KEMSA tenders are executed. Manufacturers still concerned over price-margin concessions
Kenya Health Products and Technologies Regulatory Authority (KHPTRA) Bill
Compliance with local and international standards for product quality and safety is essential.
Customs and trade regulations on the cost of importing raw materials and exporting finished goods

A hand wearing a white nitrile glove holds a clear plastic pill bottle with a black cap. The background is a blurred laboratory setting with a stethoscope and other medical equipment. The image is overlaid with a blue diagonal gradient.

3 Strategic Issues and Emerging Imperatives

3. Strategic Issues and Emerging Imperatives

3.1 Structurally misaligned Governance ecosystem and Operational architecture

- Kenya signals strong LM mandate without capable delivery mechanism, as national and regional calls show high-level political goodwill without unequal delivery architecture with real execution capacity and capability.
- Constraints do not fall solely within the remit of any one ministry, and the resulting industry challenges are shared across all relevant MDAs. Nonetheless, some broad interventions continue to be framed as sector specific programmes rather than as coordinated, cross government or cross sectoral initiatives, limiting the collective ability to address systemic issues effectively.
- Unevenly stacked ecosystem still struggling with cross-sector regulatory policy congruence, institutional strengthening and coordination. While political signal shows value at regional level, the local ecosystem is not aligned with the regional frequency for LM as a driver of affordable UHC and socio-economic growth. Figure 22 shows systemic factors impacting advancement of LM, which must be addressed holistically through coordinated, focused, and time-bound actions. Fragmented data systems architecture, limited governance, standards, trust, and transparency to ensure desired systems framework links policy to practice galvanizing public and private actors to move in the same direction.
- Structural barriers (e.g. Cross MDA ambiguity, duplication, coordination gaps, limited fiscal space amidst uncertainty and risk perception of LM attractiveness), fragmented HPT market and access development (e.g. slow, lengthy public procurement, payment delays, sustainable health financing); Limited investment due-diligence and articulate requirements for credible investment program to guarantee funds absorption capacity; Infrastructure insufficiency; Limited industry-relevant skills for PVC levels 4 and 5, amidst transition risks;
- Insufficient investment in scientific innovations in Product development and R&D culture, partly due to tight fiscal space, misaligned skills versus industry needs, limiting competitiveness locally driven yet globally connected HPT production capacity and robust, market-aligned skilled workforce.



Figure 22: Critical Success Factors for LM ecosystem growth

3.2 Conflicting and/or regressive cross-sectoral policy for the same common LM agenda.

- Underlying systemic fiscal trap between revenue survival today and industry growth going forward, leading to antagonistic economic forces pulling in opposite directions. There is persistent “push-pull” balancing act between sustaining competitiveness and growth of LM industry through robust fiscal incentives and tax concessions versus enabling government to be adequately resourced through increased taxes to overcome revenue survival and debt burden in order to achieve and deliver on its core mandate and functions.
- Anchoring fiscal incentives in annual tax policy shifts dis-incentivizes private sector actors and lead to business planning uncertainty. One year is hardly enough for LM industry to gain traction. While resource mobilization is a priority to aid financing of Government budgetary or development goals and recurrent operations, it often comes at the expenses of dis-incentivizing the growth of LM industry. Manufacturing sector like Pharma LM are the wealth generators and providers of skilled employment for Kenya economy whose unemployment levels remain a matter of national concern and priority. Issues cutting across VAT refunds, excise duties, goods reclassification for tax applicability, turnover and withholding taxes, PAYE, Free Trade Agreements, and new fees, charges and levies imposed by different government agencies further increase uncertainty in business planning and cost of doing business for Local Manufacturers.

- Transparent roadmap needed for ML3 (PPB) and GMP pathway (Local Manufacturers) to bring certainty in the LM investment landscape. Long term, these factors impact the business environment, and Kenya's attractiveness and competitiveness advantage as the preferred regional hub for local HPT manufacturing compared to other African countries.
- Need consistent regulatory pace and operational effort synonymous with health emergency response to leverage regional partnership initiatives to mobilize resources and galvanize quick-win incentive schemes to seed capital for interested local manufacturers (i.e. blended, concessional, and debt). Partner funders prefer credible alignment between unit economics versus operational structures and regulatory ease of doing business (e.g. *contextual or actual industry cost structures/incentives that don't distort investment signals and industry sustainability*). Non-volatility regulatory environment leads to sound industry governance and strategic integrity in market assurance, return on investment, and industry outlook that is both profitable at the topline and not value-destructive at the bottom-line. At present, the declining PPI (producer price index) for local manufacturers is not a positive outlook.
- Regulatory strand is the most challenging component in the entire HPT product development and commercialization lifecycle ecosystem, with vaccines lasting up to 15 years and diagnostics up to 5 years before commercial traction can be achieved. This is unattractive to private (risk-based) capital.

3.3 Local manufacturing capacity sizing, utilization, and expansion

- Need for an integrated ecosystem model that includes all six critical success factors (figure 22) for sustainable value-chain and business models. Government-backed investment scheme should not just to attract actors into LM ecosystem, but present a balanced, market data backed by realities (e.g. Industry's top-performance earnings threshold versus median; True costs of participation in LM investment segment; Risks being transferred to government, investor, and public). Thus, beyond capital deployment and other ecosystems layers, market assurance is about how value is created and held across the end-to-end LM value chain as a signal of impact and building trust in HPT ecosystem to create lasting value that sustains the manufacturers' business model beyond the narratives of forecasted demand growth.
- Need policy-backed market vanguards to secure the market for local manufacturers striving to invest in upgrading their facilities (incl. protection from quality-compromised and cheap HPTs at unsustainably lower market prices). PPB regulatory capacity and supervisory actions still unable to address proliferation of counterfeit imports to sustain growth of legitimate local manufacture and restore public confidence. Assured high quality at affordable prices requires upgraded skills and infrastructure. Government MDAs must coordinate to support LM industry to enable efficient local manufacturers to invest in high quality production, and enforcement of quality standards is a critical in addressing this challenge.
- Needs robust viability analysis e.g. infrastructure economics, procurement design, demand uncertainty, technology access, financing, regulatory support, ecosystem readiness, regional market access design for some product categories in case domestic demand along is insufficient for the assumed capacity.
- Need to broaden logic and recognition that some HPT value pools and value-chains will only become viable with assured regional market access beyond potentially constricted local market demand (especially HPTs that Kenya alone may not have sufficient scale to support regionally competitive LM unit economics).
- Need to include sustainability, ESG and climate consideration (e.g. green production and healthcare delivery) within the broader LM agenda despite Kenya being a globally vocal advocate and leading climate actor.

3.4 Market assurance and coordination weakness and gaps in progressing LM agenda

- Consider decoupling PVC level 2 and 3 approaches from the PVC level 4 and 5 approaches to have engagement strategies for route-to-market and structure stakeholder dialogue recognizing essential business fundamentals for local manufacturers, while upholding social equity in the drive to UHC.
- Upstream design issues and systemic risks (and not downstream implementation surprises) e.g. limited access to sustainable capital due to sector unattractiveness, foreign exchange pressure, technology transfer limitations, skills shortage, regulatory challenges, fragmented demand and market, and sub-scale unit economics. Fragmented and

uncoordinated market (dominated by 80% of PPB-registered 306 local trade representatives dealing only in imports) is not helping diffuse market erosion for legitimate local manufacturers investing millions in infrastructure and compliance upgrades to meet the stringent GMP quality standards. The scourge of counterfeits and substandard products exacerbates health issues and increase unfair competition for LMs.

- Need for central coordination mechanisms for HPT market and product lifecycle ecosystem. Kenya's HPT market is complex, involving multiple diverse stakeholders e.g. manufacturers, regulator, government MDAs, wholesalers, distributors, financiers, civil society, PSM buyers, and consumers. Thus, the LM industry requires coordinated and concerted efforts across these stakeholder groups to create a thriving environment for LM industry to realize its full potential as an asset for national and regional socio-economic development.
- Adequate access to HPTs is dependent on the affordability and quality of the products. Unaffordable drugs are clearly not the solution but, equally, affordable low-quality products are not the answer either. There must be optimal balance between producing high quality drugs at competitive prices in the drive for local manufacturing of pharmaceuticals.
- Need analytically prioritized HPT value-pools for short-, medium-, and longer-term planning, to enable cross linking of market shaping with planning infrastructure facility and capacity.
- Inadequate access to essential HPTs is a key limitation impacting on population's health in Kenya and regionally. Reliance on donor funding is no longer sustainable in the long term as recent geopolitical shift has restricted funding availability for procurement and supply of HPTs. Further, despite numerous diseases for which pharmaceuticals are key treatments, access to quality products is still much less advanced. National and regional efforts have identified the local production of essential drugs as an important component of a long-term solution to the provision of adequate and affordable healthcare regionally.

4

Strategy Development - Pillars, Goals, Result Areas

4. Strategy Development - Pillars, Goals, Result Areas

4.1 Anchoring the LM Strategy

The MOH leadership reaffirmed Government commitment to prioritize commodity security as a key pillar of healthcare delivery towards UHC goals through resilient systems that secure access to essential HPT, renewed leadership, discipline, innovation, and alignment in HPT management and market coordination. The realization of these aspirations requires a focused and critical consideration of the following factors: -

- Urgent policy reforms and harmonization (incl. budgetary reforms tied to measurable results)
- Governance redesign and strengthening for local and regional alignment.
- Re-design operational architecture for alignment with governance
- Targeted investment of resources in areas with real impact.

Achieving HPT security, social equity, and trust with stakeholders are some the defining factors for long-term sustainability, especially given the negative impact of COVID-19 pandemic that led to >70% of HPT expiries attributed to COVID supplies alone.

As such, local manufacturing, centrally managed HPT, inter-agency alignment on common national priorities, quality assurance, product safety, reliability, accessibility, and elimination of recurrent stock-out is imperative going forward. To this end, the MOH underscores the need to finalize four frameworks to consolidate HPT security and a centrally managed HPT market coordination to attain UHC goals:

- Local Manufacturing (LM) Strategy
- National HPT Supply Chain Strategy
- Pharmacy Benefits Package (review Kenya National Pharma Policy and Clinical guides)

This **Local Manufacturing Strategy** 2025-2030 aims for the following triple bottom line:

- (a) Advancing UHC agenda for healthcare affordability and accessibility
- (b) Expansion of both the local and export markets for local Kenyan manufacturers
- (c) A conducive environment for attracting and retaining local HPT manufacturing investments.

This strategy aims to catalyse LM industry's capacity to meet demand for essential HPTs, tap the benefits of trade liberalization and regional integration, and to the extent possible within its five (5) year period, cushion Kenya and the region against global disruptions and risks impacting public health across Africa.

Increased local HPT production is aimed at conferring benefits of proximity between supply and demand sources including reliable and affordable access local population, shorter, transparent, and simpler supply chains, reduced pilferage, obsolescence or product expiry. In reference to the envisaged local vaccines production, will lead to closer supply to usage points, reduced quality degradation with shortened cold-chain, better preparedness, and resilience toward future pandemics. Further, benefits for Kenya's broader socio-economic development are creation of jobs for both skilled and non-skilled workforce, technological transfer, advances in R&D and increased regional integration through trade and complementarity.

In consideration of the role of diverse actors, policies and laws that influence local HPT manufacturing, a multi-stakeholder and multi-sectoral approach anchored on an integrated, problem-solving and central platform is critical for an effective and successful implementation of this local manufacturing strategy.

4.2 Total Market-based Approach (TMA)

Desk-reviews of Kenya’s health sector policies, relevant laws and regulations, ongoing regional partner efforts to anchor and accelerate LM, report on Assessment of Local Manufacturing Capacity for Medicines in Kenya, among other relevant sector publications, public and private sector stakeholders’ engagement and strategy workshops provided the background content for crafting LM strategies.

Total market-based (TMA) approach was applied as the primary analytical framework in developing this Local HPT Manufacturing strategy. The demand and supply factors, the interplay among policies, rules, norms, government and development agencies, state and non-state providers and their contribution to HPT availability, quality and cost have been analysed.

Figure 23 shows TMA framework utilized in understanding maturity level of local (and regional) market towards crafting the most appropriate LM strategy based on the realities underlying this industry. This is a highly regulated but commercially driven industry whose business and value-chain model would best be anchored on viability and traction to meet stringent regulatory requirements amid unfair competition with imports from countries with very high protectionism policies for safeguarding their local producers.

TMA framework is designed to understand and address the key contextual factors at play in shaping the current HPT industry in Kenya. Based on external and internal analysis, Kenya’s market presents with signalling features across all layers of the framework, which blurs a clear understanding of its maturity.

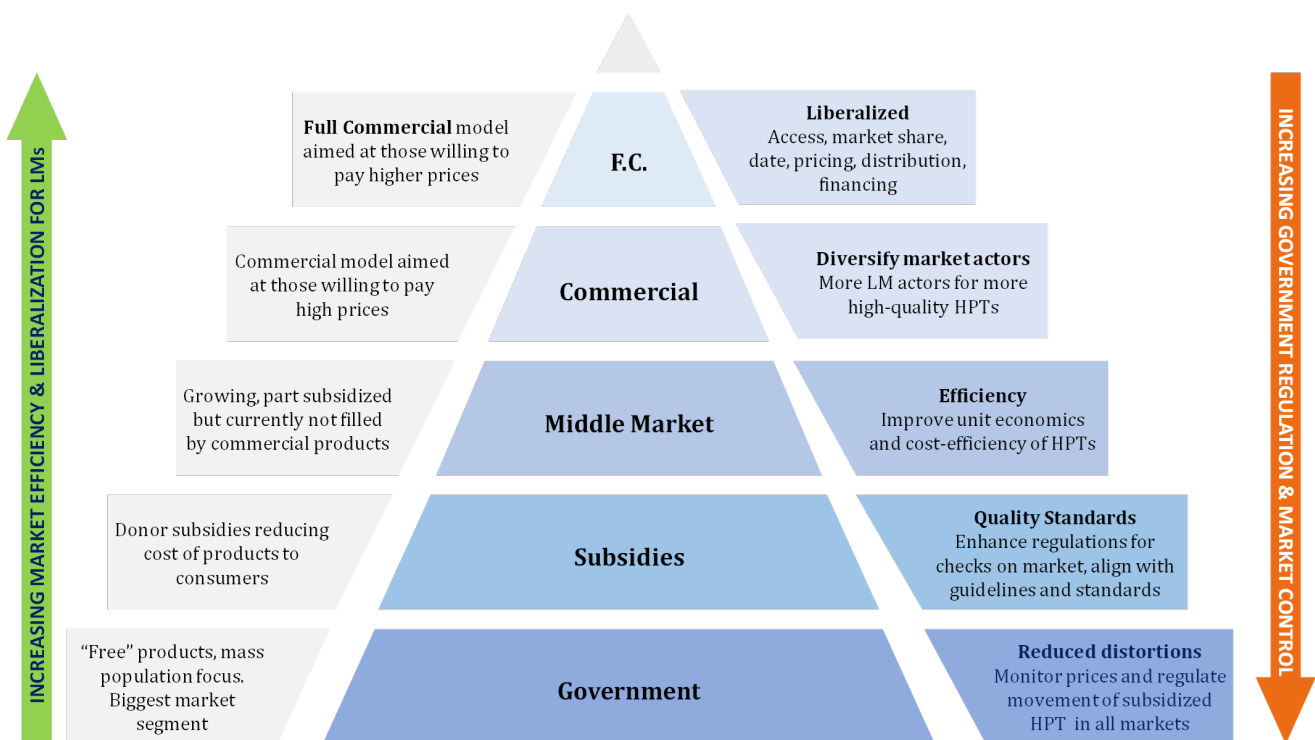


Figure 23: Total Market Approach (TMA) framework

The framework supports the design of a stronger and diversified industry that is more efficient, follows good market principles, business fundamentals and reduces distortion and HPT stock-outs across Kenya.

4.3 Composite 5-year Strategic framework

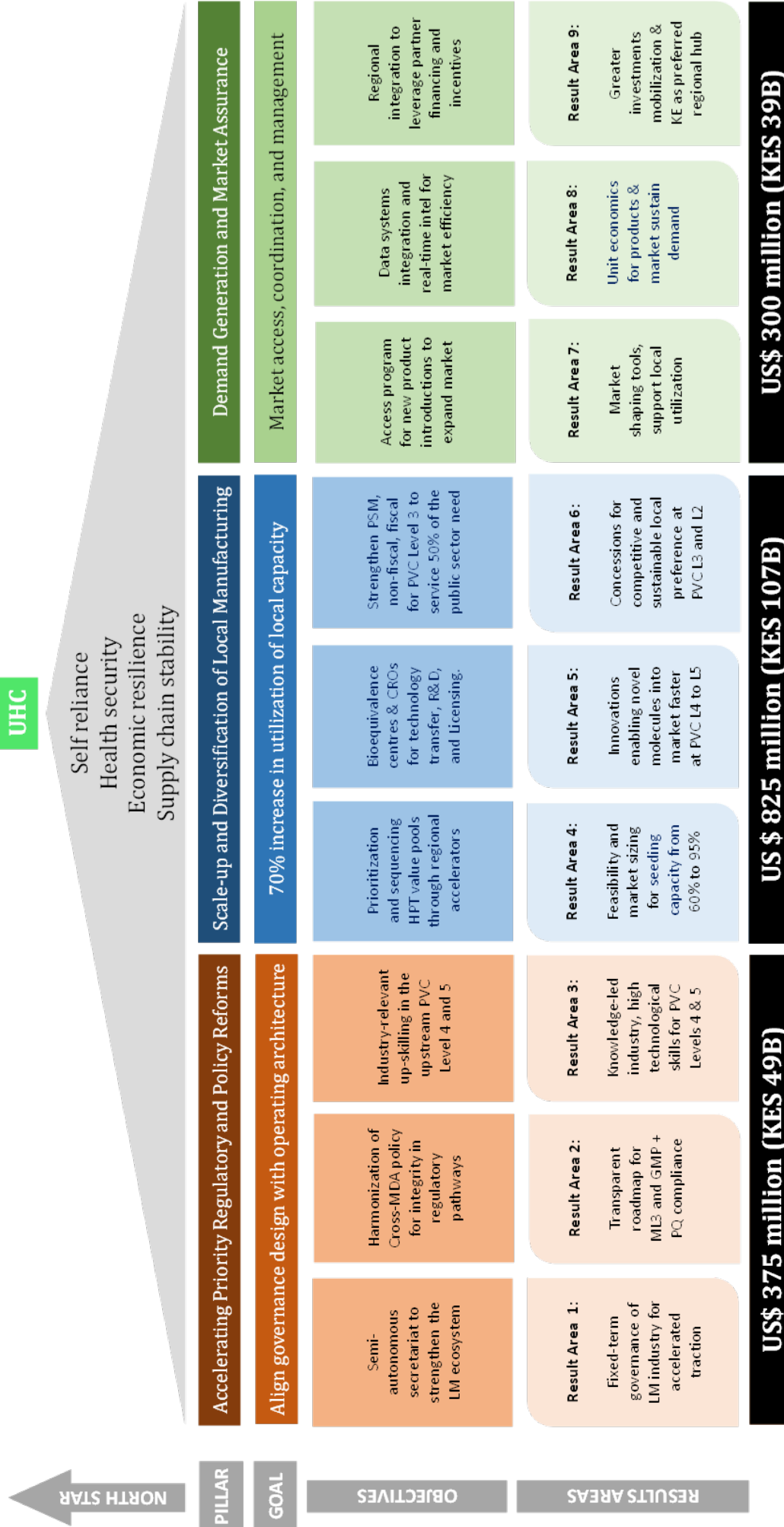


Figure 24: Composite framework of Local Manufacturing Strategy 2025 – 2030

4.4 Outcome-based Indicators for Strategic Pillars or Priorities

Table 11: Outcome-based Indicators for Strategic Pillar 1

Strategic Pillar #1		Accelerating priority regulatory and policy reforms							
Strategic Goal		Aligning LM governance design with operational architecture							
Key Objective	Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5	
Establish semi-autonomous Secretariat with cross MDA reps to strengthen the LM industry ecosystem.	RA1: Fixed term governance of local manufacturing industry for accelerated traction.	Presidential initiative to establish LM Secretariat with a 5-year mandate both as a policy & execution platform with measurable traction (annex 9.1) Independent annual review with WHO and partners on progress and course-correction State-of-Kenya-HPT-Manufacturing report with transparency on quality compliance, production, financial and market metrics Mid-year strategy review and adjustments based on emerging evidence and findings	✓	1	1	1	1	1	
Harmonization of the cross-sectoral policies on LM for integrity in the regulatory pathways	RA2: Transparent & structured roadmap toward ML3 for PPB and GMP & PQ compliance for local manufacturers	Resolution on Kenya Drugs Bill No. 54 of 2020 passed by Parliament Nov. 2024 vs. PPB Act (Cap 244 bill) amendment to align PPB's ML3 attainment timelines linked to concrete capacity building milestones (e.g. staffing, IT systems, inspection capabilities) GMP roadmap for manufacturers with milestones, timelines, and technical assistance needs for approx. 28 –to –37 local Kenyan manufacturers Intermediate target-set for GMP-compliant manufacturers per year to attain WHO-PQ Dedicated focal support team on WHO-PQ in MOH – DHPT for hands on technical assistance UNITAID-supported, Kenya-specific grant for WHO Regulation and PQ program (RPQ) Secretariat-led policy translation into practical manufacturer support, with 10 of the 30 enrolled LMs actively using waivers or incentives in 2 years Partner/CRO supported policy development for establishing Bioequivalence (BE) framework	✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓	25% - - - - - -	35% 1	50% 2	75% 3	85% 5	

Accelerating priority regulatory and policy reforms										
Aligning LM governance design with operational architecture										
Strategic Pillar #1	Strategic Goal	Key Objective	Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5
		Industry-and-market relevant upskilling in upstream PVC (value-chain) levels 4 and 5	RA3: Knowledge-led industry scaling high technological. and science skills for Level 4 and 5 for economic growth	Annual employment index for skilled jobs generated in local HPT manufacturing Country exchange program and learning collaborative LM capacity-building Biannual report on enhanced skills and capabilities of local workforce to meet the demand of evolving Local HPTs Manufacturing industry Annual capacity building in LM-and-HPT value chain modelling and due-diligence	✓ ✓	-	1	0	1	1

Table 12: Outcome-based Indicators for Strategic Pillar 2

Strategic Pillar #2		Strategic Pillar #2							
Key Objective		Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5
<p>Strategic Goal Achieve 70% increase in utilization of local manufacturing capacity</p>									
Product prioritization and sequencing via the regional accelerators to seed local manufacturing capacity for export market readiness	RA4: Feasibility and market sizing to fast-track range of HPT produced locally, technology and skills to scale local capacity utilization from 60% to 95%	HPT prioritization framework (e.g. health impact, health security relevance, viability of value-chain steps, existing capability and capacity, unmet need and demand, time to impact, policy readiness etc.)	✓	-					
		Substantive pre-investment due diligence scenario modelling of prioritized pathfinder products with economies of scale across broader value-pools and deeper business cases within each value-pool (e.g. vaccines, diagnostics, therapeutics, consumables).	✓	-					
		Secretariat-supported optimization plan for local manufacturers' production process aligned to HPT portfolios with market demand and Kenya EML	✓	-					
		Product-specific case with realistic production cost projections, market sizing and break-even analysis.		-					
		Sequenced investments-by-maturity (e.g. existing simple to complex molecules vaccines, diagnostic, therapeutics, consumables)		-					
		Cost benchmarking of imported products versus producer-price-index of locally produced HPT		-					
		Secretariat-supported commissioning of 2 local factories in priority product categories (essential medicines and medical devices)		-					
		Strategic collaborations within Trade Promotion campaigns for AfCFTA integration to amalgamate fragmented markets for economies of scale.							

Strategic Pillar #2 Scaling up and diversification of local manufacturing									
Strategic Goal Achieve 70% increase in utilization of local manufacturing capacity									
Key Objective	Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5	
Establish operational Bioequivalence centres & CROs (Clinical Research Organizations) for scaling R&D, Technology transfer, Licensing and Quality surveillance	RA5: Innovations enabling LMs to bring novel new molecules into market faster	Streamlined strategic collaborations and alliance network for capacity enhancement in R&D, Tech. Transfer, Licensing, Contract Manufacturing (EML)		-					
		Product quality compliance rates from post-market surveillance							
		Feasibility study for production of high-volume, low-complex APIs; Excipients, and Packaging.		-					
		Production capability developed for 3 priority APIs within the LM strategy period (2025 – 2030)		-					
		Business case for partner supported local/foreign technology transfer agreement on APIs with adequate annual tonnage capacity		-	1	1	2		
		Partnerships with India/China API manufacturers			1	1	1	1	1
Strengthen PSM, non-fiscal, and fiscal incentives at PVC L3 sustainability for public-sector absorption of locally manufactured HPT at >50%	RA6: Implemented concessions for competitiveness in securing market for local preference and sustainability of business model at PVC Level 3 and Level 2	Define/align portfolio in line with EML & Medical Devices, to map supply & demand cycles against current and future LM capacities/capabilities							
		Budgetary reforms for Escrow fund to underwrite payment delay by public sector to manufacturers	✓	576 days	365 days	180 days	90 days	60 days	
		TMA framework applied to anchor fundamentals of sound business practices in the LM industry	✓	-					
		Market shaping on packaging with matching incentives across Levels 2 and 3 value-chains	✓	-					
		Strengthened regulatory framework for LM value-chain to counter a \$760M or 70% import segment		-					

Table 13: Outcome-based Indicators for Strategic Pillar 3

Strategic Pillar #3		Demand generation and market assurance						
Strategic Goal		Effective market access, coordination, and management						
Key Objective	Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5
Leverage Access programs for new HPT introduction by partners to expand local and regional markets	RA7: Market shaping tools and mechanism aiding local capacity utilization in Kenya & regionally	Demand-side incentives aligned with partner-driven access initiatives (e.g. long-term offtakes, volume guarantees, and advance market commitments.) Dedicated sub-strategy for priority rapid diagnostic tests (RDTs) and medical devices	✓	-				
Data systems integration and real-time market intelligence driving market efficiency and economics	RA8: Unit economics for each product value-pool sustain HPT projected demand and market size	Regional support for diagnostic manufacturers in engineering, quality certification, demand, market access to scale local production (partner-led TA) Quantified addressable, accessible, and serviceable market by volume & value for import substitution Price monitoring observatory, tracking & publishing total cost of ownership (TCO) for imported versus locally produced HPTs Optimal route-to-market by product lifecycle (local) Export market diversification index (regional)	✓	-				
Regional integration to leverage partner incentives & financing opportunities.	RA9: Greater investment mobilization for Kenya as the preferred manufacturing hub for the regional (Center of Excellence)	Developed substantial and diversified pipeline worth >US\$ 3 billion across priority HPT value chains with over 30 local manufacturing firms Detailed investment prospectus for priority HPT-and-facilities to DFIs and investors Secretariat-facilitated unlocking of US\$ 100 million investment commitments for > 3 companies within the broader US\$ 3 Billion pipeline Financing model for priority deals GMP upgrade, Regulatory support, Facility expansion, Export financing, Credit insurance. (loan, equity, grant) HPT Manufacturing Investment Fund with private sector co-investment (co-financed by DFIs, KDC etc)	✓	-				

Strategic Pillar #3		Demand generation and market assurance						
Strategic Goal		Effective market access, coordination, and management						
Key Objective	Results Area	Outcome-based and value-creation Indicators	RRI	Year 1	Year 2	Year 3	Year 4	Year 5
		Green finance to adopt environmentally sustainable practices in LM operations (energy efficiency, waste reduction, circular economy in biodegradables etc.)		-				
		Aggregated regional demand for Kenya LM through Africa CDC Pooled Procurement Mechanism (APPM)	✓	-				
		Country-to-country NRAs collaboration promoting reliance, cooperation and joint inspections of local and regional facilities to harmonize requirements & standards for HPT assessments in common markets						
		Digitally integrated NRAs' info-sharing for efficiency in joint reviews of market authorization application						
		Localised pooled procurement hubs for regional market integrations for critical HPTs (i.e. Malaria, HIV, MCH and NCDs)						

The LM ecosystem has multiple challenges and issues that do not sit with only one ministry, department, or agency (MDA) of the government, and as a result will require interventions with multi sectoral and integrated approach in coordinating and implementing this strategy. The Ministry of Health and the Ministry of Investments, Trade and Industry are critical in the overall leadership and steering the implementation of the Strategy. For success, a proposal is made for a fixed-term Coordinating Secretariat reporting to an inter-ministerial steering committee overseeing the implementation of this Strategy and its regional integration. In addition, other government ministries and agencies, private sector, partners, and stakeholders with diverse interests and areas of expertise will be pivotal. Key actors will include: - Other MDAs, Academia, Research Institutions, Industry players, Development and Implementing Partners, Local, regional and global collaborating bodies and initiatives.

5. Implementation and Coordination Framework

5. Implementation and Coordination Framework

The timelines indicated in this framework are subject to, and may be varied depending on the availability of resources especially for Infrastructure-related projects.

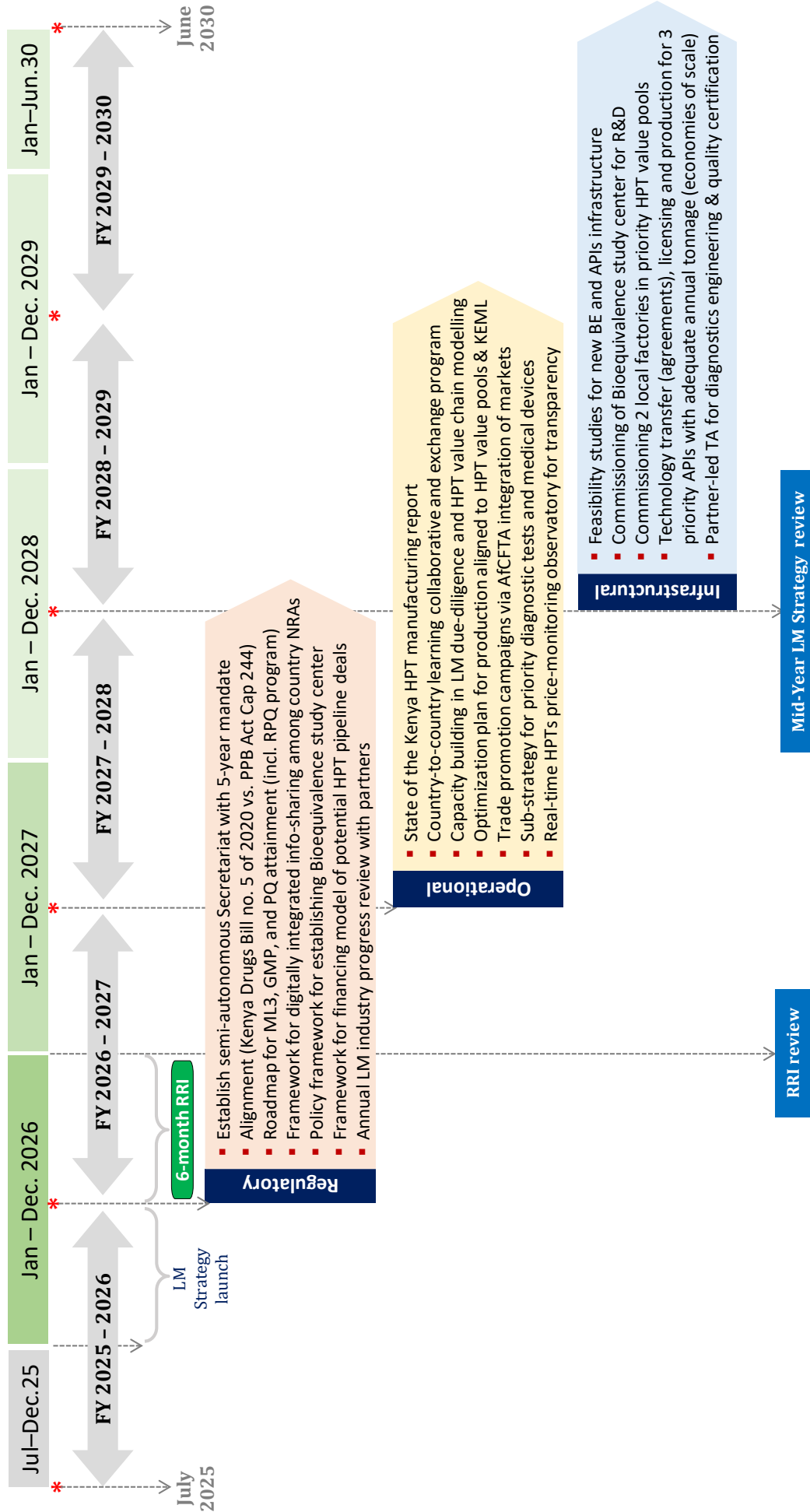


Figure 25: High-Level Implementation and Coordination Framework

The timelines indicated in this activity plan are subject to, and may be varied depending on, the availability of funds especially for Infrastructure expansion projects.

Table 14: Costed High-level Implementation and Coordination Framework

Track →	Rapid Results Initiative (RRI)	Regulatory	Operational	Infrastructural
Quantifiable Outcome – based KPIs	Semi-autonomous LM Secretariat			
	<ul style="list-style-type: none"> Engagements with Kenya Law Reform Commission (KLRC) for policy guidance & enhancement 	<ul style="list-style-type: none"> Alignment (resolution) on Kenya Drugs Bill #5 of 2020 versus PPB Act Cap 244 	<ul style="list-style-type: none"> Technology transfer, licensing and production for three 3 priority APIs with adequate scale 	<ul style="list-style-type: none"> Bioequivalence center Clinical Research Organization
	<ul style="list-style-type: none"> Policy translation into practical manufacturer enrolment and support for 10 of 30 LMs 	<ul style="list-style-type: none"> Policy framework for establishing Bioequivalence study center Roadmap towards ML3, GMP, and PQ (leveraging partner RPQ accelerator) 	<ul style="list-style-type: none"> Optimization plan for production aligned to HPT value pools & KEML 	<ul style="list-style-type: none"> Enhance two (2) local factories in priority HPT value pools
		<ul style="list-style-type: none"> Framework for digitally integrated NRAs info-sharing among countries 	<ul style="list-style-type: none"> Capacity building in due-diligence and HPT value chain modelling 	
		<ul style="list-style-type: none"> Financing model framework for potential product pipeline deals 	<ul style="list-style-type: none"> Real-time HPTs price-and-quality monitoring for transparency 	
			<ul style="list-style-type: none"> Country exchange program and learning collaborative 	
	<ul style="list-style-type: none"> Market-shaping through regional demand aggregation using Africa Pooled Procurement Mechanism 	<ul style="list-style-type: none"> Annual LM industry progress review 	<ul style="list-style-type: none"> State of the Kenya HPT manufacturing report 	<ul style="list-style-type: none"> Feasibility studies for new BE center and APIs infrastructure
			<ul style="list-style-type: none"> Sub-strategy for priority diagnostic tests and medical devices 	<ul style="list-style-type: none"> Partner-led support for diagnostics engineering & quality certification

Track →	Rapid Results Initiative (RRI)	Regulatory	Operational	Infrastructural
Deliverables or Milestone	<ul style="list-style-type: none"> Fixed-term LM secretariat Harmonized LM policy regime Expanded local/regional market 	<ul style="list-style-type: none"> Transparent roadmap for ML3, GMP, and PQ certification Frameworks for NRAs collaboration in joint reviews, BE centre, funding model. HPTs regulatory autonomy 	<ul style="list-style-type: none"> Trade promotion campaigns through AfCFTA markets-integration agenda KEML-aligned HPTs value-chain optimization models and capacity Benchmark (learning collaborative) Medical devices sub-strategy Market integration campaigns 	<ul style="list-style-type: none"> Bioequivalence study centre Signed (tech-transfer, licensing, production) agreement for 3 APIs TA & funding unlocked for value pools in APIs and Diagnostics Two (2) facilities upgraded
Responsibility	Secretariat, LMs, Partners	Secretariat, LMs, Partners	Secretariat, LMs, Partners	Secretariat, LMs, Partners
Budget Estimate	KES 2.6 billion (US \$ 20 million)	KES 7.15 billion (US \$ 55 million)	KES 8.45 billion (US \$ 65 million)	KES 176 billion (US \$ 1.36 billion)
Duration	6 months (RR1) – 15 months (RR2)	35 months	48 months	48 months
Start Period	July 2026	August 2026	July 2026	July 2026
End Period	December 2027 (Sustain)	June 2029	December 2028	June 2030

6. Risk Management Framework

6. Risk Management Framework

Implementation of this strategic plan is susceptible to institutional and LM ecosystem risks. This section highlights some of the risks and their potential impact. The main risks (i.e. operational, financial, compliance, stakeholder, environmental, social, governance, and reputational) that may affect the successful implementation of this strategic plan are outlined in the Table 15 below:

Table 15: Strategic Risk Management and Mitigation Framework

(A) Types of risks	Strategic Risk Identification and Scoring (Risk Profiling)					Strategic Risk Management Plan (Prevention or Mitigation Measures)							
	(B) Description of the risk	(C) Risk likelihood	(D) Risk impact	(E) Risk level (rating)	(F) Risk owner	(G.1) Task	(G.2) Milestone	(G.3) When / How often	(G.4) Who	(G.5) Status of the task	(C) Risk likelihood after mitigation	(D) Risk impact after mitigation	(E) Risk level after mitigation
Governance	Misaligned strategy goals versus legal entities' mandates	Likely	Very High	High	DHPT	Draft MOU with scope	Policy brief	Once	Steering team	Not started	Likely	Very High	High
Governance	Systemic constraint with integration	Almost Certain	Very High	High	Steering team	Review end of Q2-2026	Evaluation of the RRI	Biannual	Steering team	Not started	Possible	High	Moderate
Governance	Unmet stakeholder expectations of LM	Possible	Moderate	Moderate	DHPT	Consensus building	Town hall meetings	Annual	Steering team	Not started	Likely	Very High	High
Governance	Delay in regulatory policy reforms	Almost Certain	Very High	High	DHPT PPB	Engage the KLRC	Policy action	Annual	Steering team	Partly started	Possible	Very High	Moderate
Operational	Budget constraints or inefficiencies	Almost Certain	Very High	High	Steering team	Resource Mobilization	Budget reviews	biannual	Steering team	Not started	Almost Certain	Very High	High
Operational	Subjective metrics for evaluation	Possible	Very High	High	DHPT	High-level meeting	Resolution action plan	Monthly	DHPT	Not started	Likely	Very High	High
Operational	Staff capacity, skill gaps, or attrition	Possible	Moderate	Moderate	DHPT	Capacity building	Training	Biannual	DHPT	Not started	Possible	High	Moderate
Operational	Force majeure situations	Possible	Very High	High	Steering team	High-level meeting	Policy action	Ad hoc	Steering team	Not started	Possible	Very High	Moderate
Operational	BE, licensing, HPT lifecycle delays	Almost Certain	Very High	High	DHPT PPB	High-level meetings	Business case letter	Once-off	Steering team	Not started	Likely	Very High	High
Financial	Budget overrun or insufficiency	Almost Certain	Very High	High	Steering team	Budget reforecast	Revised budgets	Monthly	DHPT	Not started	Almost Certain	Very High	High

(A) Types of risks	Strategic Risk Identification and Scoring (Risk Profiling)					(G) Strategic Risk Management Plan (Prevention or Mitigation Measures)							
	(B) Description of the risk	(C) Risk likelihood	(D) Risk impact	(E) Risk level (rating)	(F) Risk owner	(G.1) Task	(G.2) Milestone	(G.3) When / How often	(G.4) Who	(G.5) Status of the task	(C) Risk likelihood after mitigation	(D) Risk impact after mitigation	(E) Risk level after mitigation
Financial	Forex losses due to lack of hedging	Almost Certain	Very High	High	Steering team	Policy letter to Treasury	Financial reports	Monthly	Steering team	Not started	Possible	Very High	High
Compliance	Reporting delays, unresolved query	Almost Certain	Very High	High	DHPT	High-level meetings	Resolution reports	Once-off	DHPT	Not started	Possible	Very High	High
Compliance	Non-compliance with requirements	Likely	Very High	High	DHPT PPB	Review call or meeting	Action items	Once-off	DHPT PPB	Not started	Possible	Very High	Moderate
Compliance	Legal breaches	Almost Certain	Very High	High	DHPT PPB	3rd party review	Legal notes	Once-off	PS Medical Services	Not started	Possible	Very High	Moderate
Stakeholder	Lack of stakeholder group engagement	Possible	Very High	Moderate	DHPT PPB	Alignment engagement	Minutes of meeting	Once-off	DHPT PPB	Not started	Likely	Very High	High
Stakeholder	Conflicts of interest	Almost Certain	Very High	High	DHPT PPB	Investigate for action	Publish findings	Once-off	DHPT PPB	Not started	Possible	Very High	High
Stakeholder	Changes in government policy or priorities	Almost Certain	Very High	High	Steering team	Consensus meetings	Policy action	Once-off	Steering team	Not started	Rare	Very High	Moderate
Environment and social	ESG impacts of HPT expiries	Almost Certain	Very High	High	PPB, LM KEMSA	Review ESG metrics	Sustainable provisions	Monthly	Steering team	Not started	Possible	Very High	High
Environment and social	Social or political disruptions	Possible	Very High	High	Steering team	Emergency meetings	Situation Review and alerts to all	Ad hoc	Steering team	Not started	Likely	Very High	High
Environment and social	Divergence from global treaties	Almost Certain	Very High	High	Steering team	Leadership alignment	Policy action	Ad hoc	Steering team	Not started	Likely	Very High	High
Reputational	Unresolved LM actors' concerns	Almost Certain	Very High	High	Steering team	Town hall meeting	Policy action	Annual	Steering team	Not started	Possible	Very High	Moderate
Reputational	Competing priority or MDA conflicts	Almost Certain	Very High	High	Steering team	Town hall meeting	Policy action	Annual	Steering team	Not started	Possible	Very High	Moderate
Reputational	Misuses of funds or misappropriation	Almost Certain	Very High	High	Steering team	Investigate and formal reprimand	Policy action	Monthly	Steering team	Not started	Possible	Very High	Moderate

Note: All component under mitigation provide insight into the specific actions, outcomes, responsibilities, and frequency if progress tracking is consistently conducted to manage the identified risks effectively. This will ensure all activities are clearly understood and assigned, focusing on timely and successful risk mitigation to LM strategy.

(A) Types of risks

- **Governance:** affecting the achievement of strategic goals and objectives (e.g. implementation delays, misaligned priorities or expectations, etc.)
- **Operational:** arise from day-to-day activities (e.g. inefficient resource allocation, supply chain disruption, staff or institutional capacity gaps, etc.)
- **Financial:** e.g. budget overruns, fraud or corruption, misappropriations, currency fluctuations)
- **Compliance:** adherence to regulations, standards, and requirements (e.g. non-compliance with regulations, legal or contractual obligations, reporting delays, etc.)
- **Stakeholder:** arising from relationships with key stakeholders (e.g. lack of stakeholder-group engagement, conflicts of interest, changes in government policies and priorities, etc.)
- **Environmental and Social:** relate to environmental or social issues that may impact LM industry (e.g. negative environmental impacts, social unrest or political instability, unaddressed cultural or gender sensitivities, etc.)
- **Reputational:** relating to the reputation of the government, the MOH, partners, or stakeholders (e.g. public criticism, negative media coverage, allegations of misconduct, etc.)

(B) Description of the risk

Concise explanation of potential issue that may negatively impact strategic plan implementation (i.e. what could go wrong, underlying cause, and possible consequences). The description helps clarify the nature of risk and informs stakeholders why it’s a concern. This aids its assessment and management.

(C) Risk likelihood categories (Probability of occurrence)

- **Rare (1/5):** Very unlikely to happen; exceptional circumstances.
- **Unlikely (2/5):** Could happen but not expected.
- **Possible (3/5):** Might occur at some point.
- **Likely (4/5):** Will probably happen in most circumstances.
- **Almost Certain (5/5):** Expected to happen regularly.

(D) Risk classification categories (Impact)

- - **Insignificant:** No effect.
- - **Minor:** Minor inconvenience; unlikely to affect strategic goals significantly.
- - **Moderate:** Could disrupt interventions or timelines but manageable within existing plans.
- - **High:** Major disruption that could delay or jeopardize outcomes or require major changes.
- - **Very High:** Catastrophic impact; could cause the Strategy to fail or be discontinued.

(E) Risk level

The risk level helps to rank risks and prioritize mitigation action, and it is defined by combining the estimated impact and likelihood and is assessed on a four-point scale as per below:

Table 16: Matrix for Risk Appetite Rating and Tolerance for Uncertainty

Likelihood	5. Almost Certain	Moderate	Moderate	High	High	High
	4. Likely	Low	Moderate	Moderate	High	High
	3. Possible	Low	Moderate	Moderate	Moderate	High
	2. Unlikely	Low	Low	Moderate	Moderate	Moderate
	1. Rare	Low	Low	Low	Low	Moderate
		1. Insignificant	2. Low	3. Moderate	4. High	5. Very High
		Impact				

(F) Risk owner

The person or entity accountable for managing a specific risk, and responsible for ensuring that the risk is properly assessed, monitored, and that actions are taken to mitigate or manage the risk.

(G) Preventive or Mitigation Measures:

Action to prevent risk from occurring (preventative) or minimize impact if it does occur (mitigation).

(G.1) Task: A specific action or step that needs to be taken to prevent or mitigate the identified risk.

(G.2) Deliverable: The tangible outcome or product of the task, such as a report, completed process, or implemented control, that demonstrates the task has been completed.

(G.3) When / Frequency: The timeline for when the task needs to be completed, or how often it should be performed (e.g., one-time or once-off, monthly, biannually, annually, or ad hoc).

(G.4) Who: Individual or team responsible for executing the task and ensure mitigation measure is implemented.

(G.5) Status of the Task: An update on the progress of the task, such as whether it is completed, in progress, delayed, or not started. This helps track the implementation of mitigation actions. Updates provided in this column should always include a reference to the date on which update is provided.



7. Resource Requirement and Mobilization

7. Resource Requirement and Mobilization

Purpose:

Translates Implementation and Coordination Framework (Table 13) in section 5, into costed delivery roadmap outlining budgets for each track. Breakdown of budget by track, by strategic pillar or priority areas, and where funding will be sourced are detailed in Table 16 below.

Scope:

Budget covers the full set of inputs required to successfully execute the strategy (i.e. secretariat processes, external activities, manufacturing facility upgrades, Bioequivalence centre, quality-assurance laboratory upgrades, regulatory improvements, project management, controls, and risk assurance etc.)

Cost-build methodology:

Derived bottom-up from simple, observable drivers, applicable unit rates, with explicit, sized risk allowances by package. No top-down mark-ups are used in this process.

Proposed funding structure:

a) Development Finance Institutions (DFIs) and Implementing Partners

To support Secretariat, RRI activities and operational track as the government budgeting cycle is restrictive to a set calendar and inflexible to meet the ambitious short-term aspirations.

b) Government funding and public-private-partnerships (PPP's)

To support regulatory track including through legal technical assistance or advisory support as most activities will involve cross ministries, department, and agency (MDA) engagements.

c) DFIs, Implementing Partners and PPP's

To support capital works i.e. infrastructure upgrade and new developments, licensing and technology transfer, governance, digital systems, accreditation, regulatory technical assistance and capability building.

Sequencing and conditions precedent:

- Progress in all tracks are contingent upon establishment of a Secretariat by Presidential order.
- RRI, Operational, and Infrastructure tracks depend on certain regulatory hurdles being addressed.
- Infrastructure track is *funding-contingent*, only after infrastructure fund mechanism is established.

Governance and assurance:

Expenditure on all tracks follow laid down PFMA procedures with full audit trails and accountability to all partners and stakeholders, with Steering Committee and Secretariat as dual overseeing entities. Contingency must be held inside each track and released only against validated or signed-off evidence.

Table 17: Estimated budget by Track for Costed Implementation and Coordination Plan


By Track or Strand	KES (billion)	USD (million)	Proposed source of funds
Rapid Results Initiative	2.60	20	GoK, DFIs and Implementation partners
Operational	7.15	55	Gok, DFIs and Implementation partners
Regulatory	8.45	65	GoK, DFIs and Implementing partners
Infrastructural	176.00	1,360	GoK, DFIs, Implementation partners (PPP)
Grand total (KES - billion)	194.20	1,500	

Table 18: Estimated budget by Strategic Pillar for Costed Implementation and Coordination Plan

By Strategic Pillar or Priority	KES (billion)	USD (million)
1. Accelerated Priority Regulatory and Policy Reforms	48.55	375
2. Scaling-up and Diversification of Local Manufacturing Capacity	106.81	825
3. Demand generation and Market Assurance	38.84	300
Grand total (KES - billion)	194.20	1,500

Table 19: Resource mapping against estimated budget breakdown by HPT value-pools

CAPEX and OPEX for HPT value pools of interest (in USD million) and Resources Mobilized						
HPT value-pools	Total Budget	GoK commitment	Partner commitment	Resource gap	Resource mapping (Annex 9.3, Table 23)	
Therapeutics pool	\$ 593.94	\$ -	\$ -	\$ 593.94	UNITAID's RMEA (MedSuRe) focused on Therapeutics e.g. HIV treatments, Anti-Malarials, PPH medicines; Govt. of Kenya (\$380M committed); Govt. of South Korea (ECDF \$210M committed); AfDB \$300M yearly (2020-2030) to develop Pharma & Vaccines industry directly (To seed and create R&D capacity, quality standards, regional supply chain logistics trade integration, and infrastructure development);	
Bioequivalence Lab	\$ 15.00	\$ -	\$ 1.83	\$ 13.17		
Smart Vaccine facility	\$ 248.00	\$ 38.00	\$ 210.00	\$ -		
2 Vaccines Tech. transfers	\$ 20.00	\$ -	\$ -	\$ 20.00	GAVI's USD 1.2B Africa Vaccines Manufacturing initiative (UNICEF tender)	
Diagnostics pool	\$ 552.13	\$ -	\$ -	\$ 552.13	UNITAID's RMEA (Manufacturing to Accelerate Diagnostics Excellence) focused on RDTs for HIV, Malaria, other priority diseases)	
Consumables + Equipment	\$ 50.19	\$ -	\$ -	\$ 50.19	World Bank's African Initiative for Medical Access and Manufacturing (AIM)	
Medical Devices pool	\$ 50.19	\$ -	\$ -	\$ 50.19	2026-2030: Build infrastructure, Create Policy Reform, Fund Program, Private-sector Partners and Mobilization (Covers Therapeutics, Diagnostics, Vaccines, BE Lab, and Regulatory affairs).	
Non-Therapeutics pool	\$ 175.68	\$ -	\$ -	\$ 175.68		
Regulatory reforms	\$ 44.70	\$ -	\$ -	\$ 44.70		
Total Budget (USD)	\$ 1,749.83	\$ 38.00	\$ 211.83	\$ 1,500.00		



8. Monitoring, Evaluation and Reporting Framework

8. Monitoring, Evaluation and Reporting Framework

The following M&E reporting frameworks will support the LM steering committee, the coordinating secretariat, leadership and cross-sectoral teams and stakeholders to drive meaningful progress on the three (3) strategic pillars. Each framework contains detailed parameters that should not be used only as a tick-off checklist, but as thought-starters for deeper immersion in uncovering systemic blind spots and trigger better reflections and engagements across the LM ecosystem. Further, the frameworks are intended to keep the momentum on growing the LM industry, and should be applied in assessing current baseline, and where the industry needs to go. The parameters are a mix of strategic, operational, and forward-looking aspirations, aiming to address overlooked aspects in past attempts at galvanizing the LM ecosystem for growth.

Important Note: For all intents and purposes, Secretariat is the coordinating platform comprising MDAs (i.e. MOH, MITI, Kenya Biovax Institute, PPB, Treasury, KEMRI, NQCL, KEMSA, KRA). Affiliate members by Secretariat invitation may include FKPM, DFIs, KNBS, KENTRADE, Implementing Partners, MOH-Programs of prioritized HPT value-pools, KLRC, KEBS, EPZ Authority, SEZ Authority, KEPISA, KAM, NEMA, Anti-Counterfeits Authority, L6-Referral Hospitals, and Counties.

Table 20: M&E Framework: Strategic Pillar 1 (Accelerating Priority Regulatory and Policy Reform)

Outcome-based indicator	Baseline	Responsibility	Due Date
Result Area (RA) #1: Fixed-term governance of LM industry for accelerated traction			
<ul style="list-style-type: none"> Presidential initiative to establish LM Secretariat with a 5-year mandate both as a policy & execution platform with measurable traction (annex 9.1) Independent annual review with WHO and partners on progress and course-correction State-of-Kenya-HPT-Manufacturing report with transparency on quality compliance, production, financial and market metrics Mid-year strategy review and adjustments based on emerging evidence and findings 	Nil	Steering Committee and Senior Advisor	July 2026
	Nil	Secretariat, FKPM, Development Partners	June 2027
	Nil	Secretariat, FKPM, Development Partners	June 2027
	Nil	Secretariat, FKPM, Development Partners	January 2028
Result Area (RA) #2: Roadmap to ML3 for PPB and WHO-PQ for local manufacturers			
<ul style="list-style-type: none"> Resolution on Kenya Drugs Bill No. 54 of 2020 passed by Parliament Nov. 2024 vs. PPB Act (Cap 244 bill) amendment to align PPB's ML3 attainment timelines linked to concrete capacity building milestones (e.g. staffing, IT systems, inspection capabilities) GMP roadmap for manufacturers with milestones, timelines, and technical assistance needs for approx. 28 –to –37 local Kenyan manufacturers Intermediate target-set for GMP-compliant manufacturers per year to attain WHO-PQ Dedicated support team on WHO-PQ in MOH – DHPT for hands on technical assistance 	Nil	Secretariat, KLRC, Development Partners	October 2026
	Nil	Secretariat, FKPM, Development Partners	December 2026
	Nil	Secretariat, FKPM, Development Partners	June 2027
	Nil	Secretariat, FKPM, Development Partners	December 2027
	Nil	Secretariat, FKPM, Development Partners	June 2027
	Nil	Secretariat, FKPM, Development Partners	December 2026
	Nil	Secretariat, FKPM, Development Partners	December 2027
	Nil	Secretariat, FKPM, Development Partners	June 2027
Result Area (RA) #3: Knowledge-led industry, high tech. skills for PVC Levels 4 & 5			
Annual employment index for skilled jobs generated in local HPT manufacturing	Nil	Secretariat, KNBS, Ministry of Labour	December 2027
Country exchange program and learning collaborative LM capacity-building	Nil	Secretariat, FKPM, Development Partners	January 2028
Biannual report on enhanced skills and capabilities of local workforce to meet the demand of evolving Local HPTs Manufacturing industry	Nil	Secretariat, KNBS, Ministry of Labour	June 2027
Annual capacity building in LM-and-HPT value chain modelling and due-diligence	Nil	Secretariat, FKPM, Development Partners	June 2028

Table 21: M&E Framework: Strategic Pillar 2 (Scale-up and diversification of local capacity)


Outcome-based indicator	Baseline	Responsibility	Due Date
Result Area (RA) #4: Feasibility and market sizing for seeding capacity from 60% to 95%			
HPT prioritization framework (e.g. health impact, health security relevance, viability of value-chain steps, existing capability and capacity, unmet need and demand, time to impact, policy readiness etc.)	Nil	Secretariat, FKPM, Development Partners	December 2026
Substantive pre-investment due diligence scenario modelling of prioritized pathfinder products with economies of scale across broader value-pools and deeper business cases within each value-pool (e.g. vaccines, diagnostics, therapeutics, consumables).	Nil	Secretariat, FKPM, Development Partners	December 2026
Secretariat-supported optimization plan for local manufacturers' production process aligned to HPT portfolios with market demand and Kenya EML	Nil	Secretariat, FKPM, Development Partners	March 2027
Product-specific case with realistic production cost projections, market sizing and break-even analysis.	Nil	Secretariat, FKPM, Development Partners	June 2027
Sequenced investments-by-maturity (e.g. existing simple to complex molecules vaccines, diagnostic, therapeutics, consumables)	Nil	Secretariat, FKPM, Development Partners	December 2027
Cost benchmarking of imported products versus producer-price-index of locally produced HPT	Nil	Secretariat, FKPM, Development Partners	December 2026
<ul style="list-style-type: none"> Secretariat-supported commissioning of 2 local factories in priority product categories (essential medicines and medical devices) 	Nil	Secretariat, FKPM, Development Partners	December 2028
<ul style="list-style-type: none"> Strategic collaborations within Trade Promotion campaigns for AfCFTA integration to amalgamate fragmented markets for economies of scale. 	Nil	Steering Committee, Secretariat, FKPM, Development Partners	June 2027
Result Area (RA) #5: Innovations enabling LMs to fast-track novel molecules into market			
<ul style="list-style-type: none"> Streamlined strategic collaborations and alliance network for capacity enhancement in R&D, Tech. Transfer, Licensing, Contract Manufacturing (EML) 	Nil	Secretariat, FKPM, Development Partners	July 2027
<ul style="list-style-type: none"> Product quality compliance rates from post-market surveillance 	Nil	Secretariat, FKPM, Registered Trade Agents, KEBS, Anti-Counterfeits Authority	March 2028
<ul style="list-style-type: none"> Feasibility for production of high-volume, low-complex APIs; Excipients, Packaging. 	Nil	Secretariat, FKPM, Development Partners	June 2028
<ul style="list-style-type: none"> Production capability developed for 3 priority APIs within strategy period (2025–2030) 	Nil	Secretariat, FKPM, Development Partners	December 2028
<ul style="list-style-type: none"> Business case for partner supported local/foreign technology transfer agreement on APIs with adequate annual tonnage capacity 	Nil	Secretariat, FKPM, Development Partners	June 2029
<ul style="list-style-type: none"> Partnerships with India and China API manufacturers 	Nil	Secretariat, FKPM, Development Partners	July 2027

Outcome-based indicator	Baseline	Responsibility	Due Date
<p>Result Area (RA) #6: Implemented concessions for competitiveness in securing market for local preference and sustainability of business models at PVC Level 3 and Level 2</p>			
<ul style="list-style-type: none"> Define and align portfolio in line with EML and Medical Devices, to map supply and demand cycles against current and future LM capacities and capabilities 	Nil	Secretariat, FKPM, Development Partners	December 2026
<ul style="list-style-type: none"> Budgetary reforms for Escrow fund to underwrite payment delay by public sector to manufacturers 	Nil	Steering Committee and Secretariat	June 2027
<ul style="list-style-type: none"> TMA framework applied to anchor fundamentals of sound business practices in the LM industry 	Nil	Secretariat and FKPM	July 2028
<ul style="list-style-type: none"> Market shaping on packaging with matching incentives for Levels 2 and 3 value-chains 	Nil	Secretariat, FKPM, Development Partners	January 2029
<ul style="list-style-type: none"> Strengthened regulatory framework for PVC Level 2 and 3 to counter the 70% import segment worth US \$760M 	Nil	Secretariat, KLRC, FKPM	July 2028

Table 22: M&E Framework: Strategic Pillar 3 (Demand Generation and Market Assurance)

Outcome-based indicator	Baseline	Responsibility	Due Date
Result Area (RA) #7: Market shaping tools and mechanism aiding local capacity utilization in Kenya and regionally as the preferred hub			
<ul style="list-style-type: none"> Demand-side incentives aligned with partner-driven access initiatives (e.g. long-term offtakes, volume guarantees, and advance market commitments.) Dedicated sub-strategy for priority rapid diagnostic tests (RDTs) and medical devices Regional support for diagnostic manufacturers in engineering, quality certification, demand, market access to scale local production (partner-led TA) 	<p>Nil</p> <p>Nil</p> <p>Nil</p>	<p>Secretariat, KEMSA, MEDS, FKPM, Level 6 Referral Hospitals, Development Partners</p> <p>Secretariat, Device Manufacturers, KEBS, KEMRI, Development Partners</p> <p>Secretariat, Device Manufacturers, KEBS, KEMRI, Development Partners</p>	<p>June 2027</p> <p>June 2027</p> <p>June 2028</p>
Result Area (RA) #8: Unit economics for each product value-pool sustain HPT projected demand and market size			
<ul style="list-style-type: none"> Quantified addressable, accessible, and serviceable market by volume & value for import substitution Price monitoring observatory, tracking & publishing total cost of ownership (TCO) for imported versus locally produced HPTs Optimal route-to-market by product lifecycle (local) Export market diversification index (regional) 	<p>Nil</p> <p>Nil</p> <p>Nil</p> <p>Nil</p>	<p>Secretariat, Device Manufacturers, KEBS, Development Partners</p> <p>Secretariat, KNBS, Device Manufacturers, FKPM, Development Partners</p> <p>Secretariat, Device Manufacturers, FKPM,</p> <p>Secretariat, Device Manufacturers, FKPM, KENTRADE, EPZ Authority, KNBS</p>	<p>June 2027</p> <p>June 2027</p> <p>June 2027</p> <p>June 2027</p>
Result Area (RA) #9: Greater investment mobilization for Kenya as the preferred manufacturing hub for the regional (Center of Excellence)			
<ul style="list-style-type: none"> Developed substantial and diversified pipeline worth >US\$ 3 billion across priority HPT value chains with over 30 local manufacturing firms Detailed investment prospectus for priority HPT-and-facilities to DFIs and investors Secretariat-facilitated unlocking of US\$ 100 million investment commitments for > 3 companies within the broader US\$ 3 Billion pipeline Financing model for priority deals GMP upgrade, Regulatory support, Facility expansion, Export financing, Credit insurance. (loan, equity, grant) HPT Manufacturing Investment Fund with private sector co-investment (co-financed by DFIs, KDC etc.) Green finance to adopt environmentally sustainable practices in LM operations (energy efficiency, waste reduction, circular economy in biodegradables etc.) 	<p>Nil</p> <p>Nil</p> <p>Nil</p> <p>Nil</p> <p>Nil</p> <p>Nil</p>	<p>Secretariat and Development Partners</p> <p>Secretariat and Development Partners</p> <p>Secretariat and Development Partners</p> <p>Secretariat and Development Partners</p> <p>Secretariat and Development Partners</p> <p>Secretariat and Development Partners</p>	<p>December 2027</p> <p>December 2027</p> <p>June 2028</p> <p>June 2028</p> <p>June 2028</p> <p>June 2028</p>

Outcome-based indicator	Baseline	Responsibility	Due Date
<ul style="list-style-type: none"> Aggregated regional demand for Kenya LM through Africa CDC Pooled Procurement Mechanism (APPM) 	Nil	Steering Committee, Secretariat, FKPM, Device Manufacturers, Development Partners	December 2027
<ul style="list-style-type: none"> Country-to-country NRAs collaboration promoting reliance, cooperation and joint inspections of local and regional facilities to harmonize requirements & standards for HPT assessments in common markets 	Nil	Steering Committee, Secretariat, Development Partners	June 2028
<ul style="list-style-type: none"> Digitally integrated NRAs' info-sharing for efficiency in joint reviews of market authorization application 	Nil	Steering Committee, Secretariat, Development Partners	December 2028
<ul style="list-style-type: none"> Localised pooled procurement hubs for regional market integrations for critical HPTs (i.e. Malaria, HIV, MCH and NCDs) 	Nil	Steering Committee, Secretariat, Development Partners	December 2027



9. Annexes

9.1 Governance and operational structure for local-regional alignment

- **Strategic Pillar 1** → Accelerating priority regulatory and policy reforms
- **Strategic Goal** → To Align LM governance design and LM operational architecture

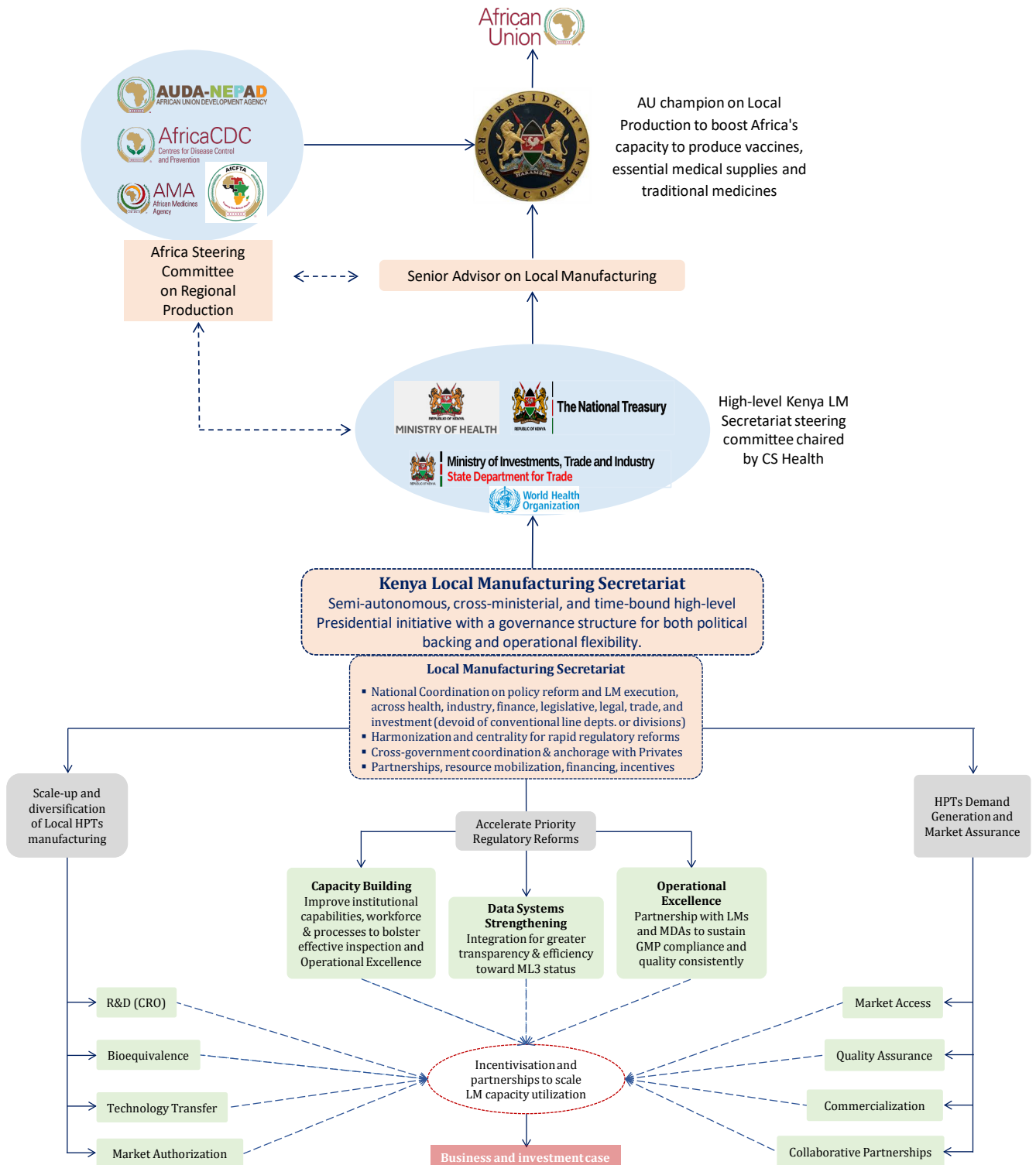


Figure 26: Proposed LM structure to align Governance Design with Operational Architecture

9.2 Detailed country case-studies and benchmarking

- **Strategic Pillar 2** → Scaling up and diversification local HPTs manufacturing capacity.
- **Goal 2** → To achieve 70% increase in utilization of local manufacturing capacity

Table 23: Summary of strategic imperatives from Country benchmarking case-studies

Context/Country	Value proposition	Policy considerations advancing local manufacturing	Strategic imperative for Kenya's local manufacturing
Nigeria case study	Presidential Initiative to Unlock Healthcare Value Chains (PVAC)	Executive Order with 2-year fixed implementation term Coordinated governance and operational architecture. Accelerated regulatory harmonization and approvals. Defined value pools (APIs, Vaccines, Dx, Syringes, Nets) Enhance PSM framework and market shaping tools	PVAC led by National Coordinator, guided by coordinating Minister (for Health) in collaboration with stakeholders & agencies (NAFDAC, Customs, Trade & Investment, Finance) Enforced fiscal and non-fiscal incentives to spur LM growth. Addressed systemic policy conflicts, poor implementation and coordination, LM under-investment due to regulatory environment, infrastructure, and services challenges. Strengthened LM for quality job creation and HPT access
Bangladesh	Turning-the-tide in 5 years (2010 – 2015)	5-year, fixed term, government-led policy enforcement Supported private sector R&D for new HPT innovations. Facilitated business linkages and Joint Ventures to meet stringent GMP standards. Financial and investment support to LMs (e.g. approval of loans, favorable interest rates, VAT waivers etc.) Implemented national policy to stop sale of some drugs. Established fixed purchase price for locally produced	Government-funded initiative to adopt modern technology and collaborate with academic research institutions. Rapidly transitioned from importing 75% of pharmaceutical needs to attaining >98% local manufacturing capacity and capability
India	Production-Linked Incentives (PLI) Scheme (2020)	PLI as a time-bound pre-committed levels of investments and production for subsidy scheme PLI introduced as a fiscal incentive scheme to advance self-reliance, employment, investment and technology. PLI differentiated as an accelerator from other traditional government-backed subsidies Promoted technologies for commercialization at large scale (e.g. high-tech products)	Limited strategic sectors eligible under PLI to attract maximum investment for incremental production, export, and employment. Fostered growth of 14 domestic industries (incl. Pharma) and enhance India's competitiveness in the global market

Context/Country	Value proposition	Policy considerations advancing local manufacturing	Strategic imperative for Kenya's local manufacturing
South Africa	Government-led initiative for local biotech talent (2001)	<p>Biotech strategy with USD 70M to catalyse development of Biotech skills, capability and tools.</p> <p>Established Regional Innovation Centres to identify and develop commercial biotech opportunities.</p> <p>Promoted curriculum development to improve science and mathematics in high-schools and encourage more students in biotech.</p> <p>Globally competitive post-doctoral bursaries to attract and retain local talent.</p>	<p>Advanced and progressed R&D, Clinical Trials, and other biotech activities</p> <p>Career opportunities for experienced and well-trained workers, and facilitated connections between experts and relevant organizations.</p>
South Africa	2003 BioVac Public Private Partnership technology transfer	<p>Government-Private investor driven mandate on vaccines R&D, manufacturing, and supply for mutual benefit (Biovac earns premium from the government on a range of vaccines to help pay for quality control and distribution fees)</p> <p>Safe fast-tracking of Biovac through technology transfer in partnership with large multinational firms to address the lack of local Biotech industry</p>	<p>Sustained vaccines flow through local supplier capacity to help reduce shortages.</p> <p>Manufacturer gains financing, reduced risks and regulatory support from government</p> <p>Improved vaccines potency and supply security for citizens</p>
Ghana	Cost-Effective Strengthening of Local Pharmaceutical Industry	<p>Long term capital at favorable interest rates to bolster local manufacturing industry.</p> <p>Short-term incentives to catalyse growth of the local pharmaceuticals production.</p> <p>Government procurement of locally produced products to support sector growth.</p> <p>Tertiary pharmaceutical schools' curricula and training programmes to meet HR requirement for the sector</p>	<p>Fostered enabling environment for advancement and sustainable development of local pharma industry.</p> <p>Innovation and technology transfer via collaborative efforts anchored under South-South cooperation.</p> <p>Sectoral support through regional harmonization of regulations at all levels of WAHO economic block</p> <p>Economical production of high-quality essential HPTs</p> <p>Marketing locally produced through regional trade shows and diplomatic endeavors</p>

9.3 Partner-led regional manufacturing initiatives prioritizing Kenya

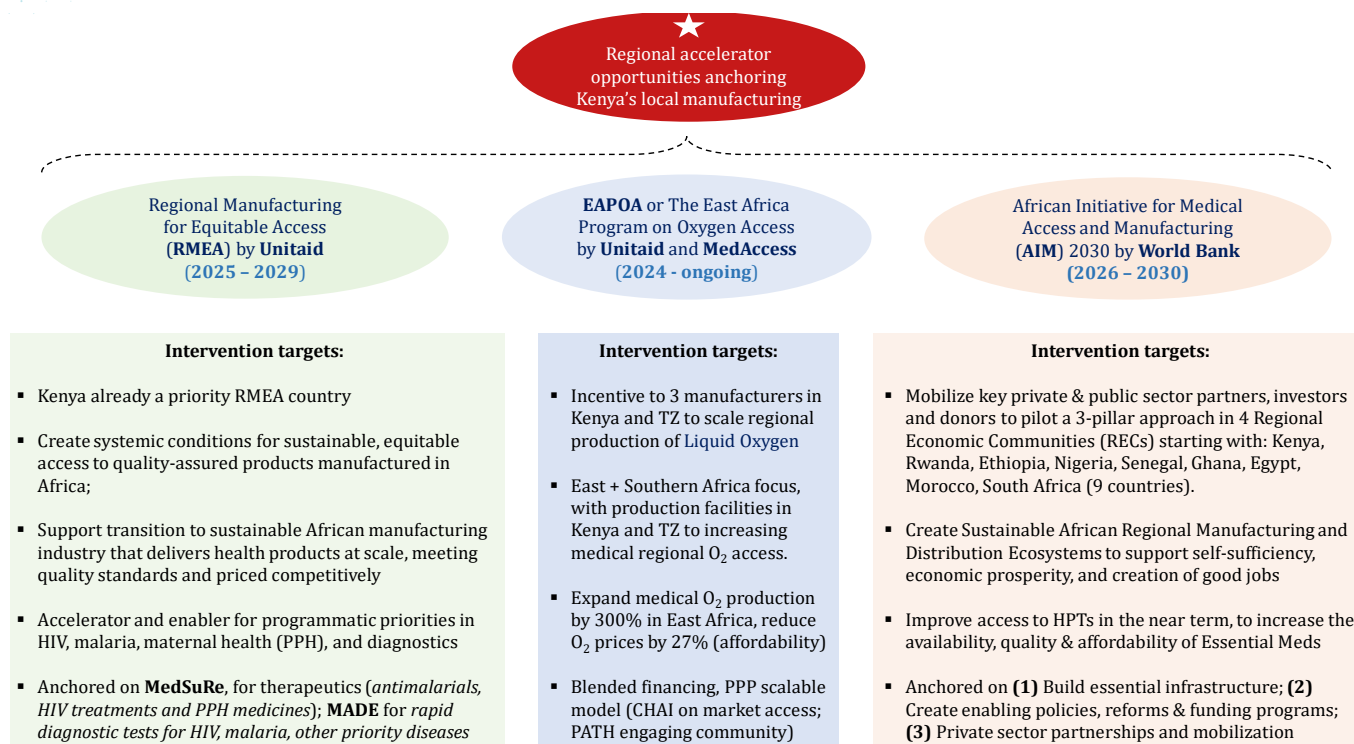


Figure 27: Partner-led regional manufacturing initiatives prioritizing Kenya

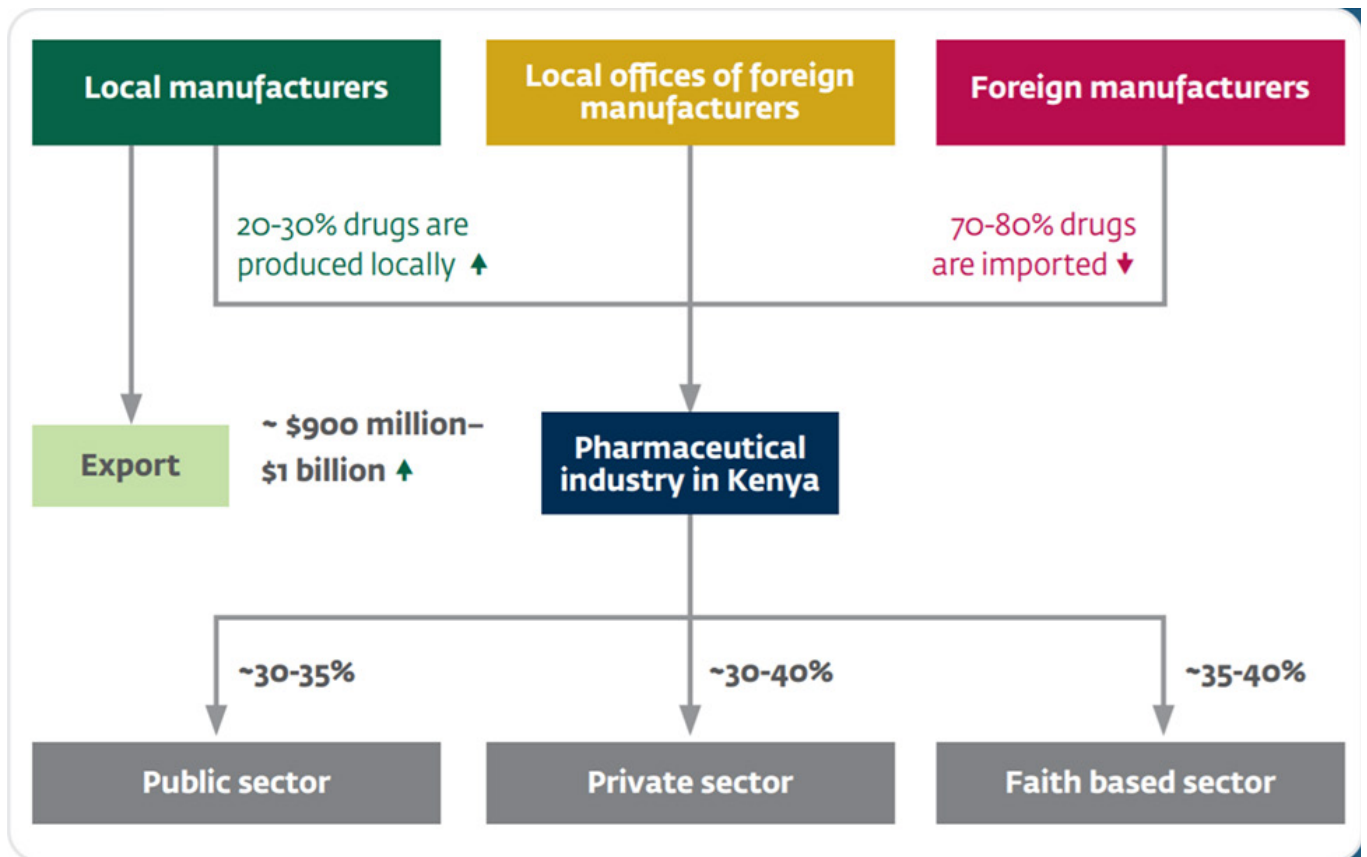
Table 24: Levers and enablers of Partner-led regional opportunities for anchoring Kenya's LM

Partner Initiative	Targets	Pillar and Levers/Enablers
East Africa Program on Oxygen Access (EAPOA) by UNITAID & MedAccess (2024 - ongoing)	<ul style="list-style-type: none"> Kenya is prioritized (East & Southern Africa as regional market of focus) Expanding medical oxygen production by 300% in East Africa (access) Reduce O₂ prices by 27% (affordability) 	<ul style="list-style-type: none"> Incentive to 3 manufacturers (2 in Kenya and 1 in Tanzania to scale regional production of Liquid medical O₂) Production infrastructure facilities built in Kenya and Tanzania to increasing regional medical O₂ access Blended financing through PPP scalable model CHAI leading on market access and shaping PATH leading on community engagement
African Initiative for Medical Access and Manufacturing (AIM) 2030 by World Bank (2026 – 2030)	<ul style="list-style-type: none"> Kenya is prioritized Mobilize private and public sector partners, investors, and donors to pilot a 3-pillar approach in 9 countries in 4 Regional Economic Blocks: <ul style="list-style-type: none"> Kenya, Rwanda, Ethiopia. Nigeria, Senegal, Ghana. Egypt, Morocco. South Africa. 	<p>a) Building the Essential Infrastructure:</p> <ul style="list-style-type: none"> Human Capital: skills development in procurement, clinical R&D, regulatory, manufacturing, supply chains Physical Infrastructure: (testing labs, (warehousing and logistic centres, manufacturing facilities' access to roads, utilities, energy, waste management etc.) Digital Infrastructure (Digital solutions for efficient regulatory, distribution, and manufacturing systems) <p>b) Create Enabling Policies, Reform & Funding Programs</p> <ul style="list-style-type: none"> Regulatory strengthening, capacity building & regional harmonization Facilitate inter-Africa trade through removal of trade barriers & creation of regional partnerships

Partner Initiative	Targets	Pillar and Levers/Enablers
	<ul style="list-style-type: none"> • Improve access to health products in the near term, focusing on increasing availability, quality and affordability of Essential Medicines • Create Sustainable Regional Production and Distribution Ecosystems to contribute to Africa's self-sufficiency, creation of good jobs & economic prosperity 	<ul style="list-style-type: none"> • Enabling policies to develop and retain skills • Strengthened procurement for demand predictability • Sustainable demand financing and market shaping mechanisms (pooled procurement, at-risk financing) <p>c) Private Sector Partnership and Mobilization</p> <ul style="list-style-type: none"> • Facilitate tech transfers: Partnerships with MNCs local and regional players, international org's, academia • Centers of Excellence for manufacturing, supply, logistics, distribution, per each country's core strengths, competencies • Blended finance and technical assistance for local manufacturing and distribution companies • Facilitate improved access to raw materials: Pooled procurement of APIs and supplies for production • Industry led skills programs in collaboration with private sector, philanthropy and academia
<p>Regional Manufacturing for Equitable Access (RMEA) by UNITAID (2025 – 2029)</p>	<ul style="list-style-type: none"> • Kenya is prioritized, with 1 of only 5 WHO PQ certified in Africa (due diligence for additional manufacturers) • Create systemic conditions for sustainable, equitable access to quality-assured HPTs produced in Africa. • Support transition to sustainable manufacturing industry in Africa towards delivering HPTs at scale, meets quality standards and priced competitively. • Accelerator and enabler for programmatic priorities in HIV, malaria, maternal health (PPH), and diagnostics 	<ul style="list-style-type: none"> • Anchored on MedSuRe (Medicines Supply Resilience Africa), focusing on therapeutics incl. antimalarials, HIV treatments and PPH medicines). • Anchored on MADE (Manufacturing to Accelerate Diagnostics Excellence), focusing on diagnostic (rapid diagnostic tests for HIV, malaria, other priority diseases • Support African manufacturers to achieve WHO Prequalification and international quality standards. • Tech. transfer for APIs, complex formulations & diagnostics • Strengthen regulatory harmonization and streamline market entry. • Catalyze demand through pooled procurement mechanisms (e.g., Africa CDC's APPM) • Promoting climate-smart, lower-carbon manufacturing • Building pandemic preparedness capacity through diversified manufacturing.

Partner Initiative	Targets	Pillar and Levers/Enablers
<p>24-priority medical products list and a roadmap for regional manufacturing by AUDA-NEPAD</p> <p>(Agenda 2063’s Second Ten-Year Implementation Plan by Africa Union)</p>	<ul style="list-style-type: none"> • Self-reliance in the African pharmaceutical industry. • Scale up local production of essential drugs, vaccines & health products critical to public health (given Africa’s growing population and disease burden). • Address the structural, IP, regulatory, and financial challenges impeding Africa pharma manufacturing. • Foster collaboration among Member States, Regional Economic Communities (RECs), and private sector to build a resilient pharma manufacturing ecosystem. 	<ul style="list-style-type: none"> • Strategic guide to pharma manufacturing stakeholders on areas needing focused investments to spur development of the sector. • Guide policymakers at continental, RECs and national level on priority medical products to provide incentives to in order to achieve greater health and economic impact. • Insights to policymakers and pharmaceutical manufacturers into products with specific supported projects strategically leveraging these resources to accelerate their own efforts and contribute to the growth of regional pharma production. • Maximize the benefits of supportive global health initiatives, leveraging available opportunities, identify synergies and remove any duplication of efforts in pharma manufacturing on the continent. • Improving access to raw materials, facilitating market access, enhancing human capital development, and fostering PPP’s.
<p>10-year Continental Pharmaceutical and Vaccine Production Vision and Action Plan by AfDB or African Development Bank</p> <p>(2030)</p>	<ul style="list-style-type: none"> • Invest \$3.1 billion by 2030. • \$100 million annually to finance development of the pharma industry directly. • \$200 million annually to support infrastructure development to help ease logistics and supply chain. 	<p>Increase the maturity of the pharma industry by supporting the development of local production capacities.</p> <ul style="list-style-type: none"> • Regional logistics integration to foster intra-African trade and creation of trade hubs. • Implementation of quality industry standards. • Seeding the creation of R&D capacities focusing on Africa specific diseases and needs. • Pave the way for increased vaccines manufacturing in Africa.

9.4 Kenya’s current HPT landscape and product value-pools



- Top products manufactured by local manufacturers: -**
- Analgesics
 - Antacids, antiflatulants, and antipeptic ulcerants
 - Antiasthmatics (bronchodilators, respiratory stimulants)
 - Antibiotics, chemotherapeutics, dermatological
 - Antiprotozoal (amoebicides, antibacterial)
 - Antihistamines for systemic use
 - Antiseptics and disinfectants
 - Cough and cold preparation
 - Cryogenics (Liquid Oxygen)
 - Systemic antimycotics
 - Systemic chemotherapeutics
 - Syringes

Figure 28: Kenya’s current HPT landscape and value pools of products

9.5 List of Stakeholders Engaged in the Development of the Strategy

Table 25: List of Stakeholders Engaged in Strategy Development

Stakeholder	Engagement channel
AMREF	Presentation at the kick-off workshop
Energy and Petroleum Regulatory Authority (EPRA)	Presentation at the kick-off workshop
Federation of Kenya Pharmaceutical Manufacturers (FKPM)	Presentation at the kick-off workshop
Hewatele	Presentation at the kick-off workshop
Jomo Kenyatta University of Agriculture and Technology (JKUAT)	Presentation at the kick-off workshop
Kenya Biovax Institute (KBI)	Presentation at the kick-off workshop
Kenya Medical Research Institute (KEMRI)	Presentation at the kick-off workshop
University of Nairobi (UoN)	Presentation at the kick-off workshop
Kenya Medical Supplies Authority (KEMSA)	Presentation at the kick-off workshop
Kenya Export Promotion and Branding Agency (KEPROBA)	Presentation at the kick-off workshop
Kenyatta University	Presentation at the kick-off workshop
Kenyatta University Teaching, Research and Referral Hospital (KUTRRH)	Presentation at the kick-off workshop
Ministry of Investment, Trade and Industry	Presentation at the kick-off workshop
PATH	Presentation at the kick-off workshop
Pharmacy and Poisons Board (PPB)	Presentation at the kick-off workshop
United States International University-Africa (USIU-A)	Presentation at the kick-off workshop

9.6 LM Strategy Development Secretariat and List of Contributors

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