AUDIT OF THE STATUS OF LOCAL MANUFACTURING OF ARVs FOR PLHIV IN KENYA

Key Findings and Recommendations

KELIN
Reclaiming Rights, Rebuilding Lives

aidsfonds

Table of Contents

List of Tables

Abbreviations & Glossary of Terms

D4T	–	Stavudine (ARV)
3TC	–	Lamivudine (ARV)
AIDS	–	Acquired Immune Deficiency Syndrome
ART	–	Anti-Retroviral Therapy (or Treatment)
ARVs	–	Anti-Retroviral (Drug or Medicine)
APIs	–	Active Pharmaceutical Ingredients
CSO	–	Community Service Organization
CAPEX	–	Capital Expenditure
COVID		Corona Virus Disease (COV-SARS-2)
EAC	–	East Africa Community
EOI	–	Expression of Interest
FKPM	–	Federation of Kenya Pharmaceutical Manufacturers
FDA	–	Food and Drug Authority (drug regulatory standard of the United States)
FDIs	–	Foreign Direct Investments
FY	–	Financial Year
GDP	–	Gross Domestic Product
GMP	–	Good Manufacturing Practices
GoK	–	Government of Kenya
GSK	–	GlaxoSmithKline
GWP	–	Good Warehousing Practice
HIV	–	Human Immuno-deficiency Virus
JV	–	Joint Venture
KASF	–	Kenya Aids Strategic Framework
KEMSA	–	Kenya Medical Supplies Authority
KPSDS	–	Kenya Pharmaceutical Sector Development Strategy
LM/LPP	–	Local Manufacturing / Local Pharmaceutical Production
MOD	–	Ministry of Défense
MOF	–	Ministry of Finance (Treasury)
MOFA	–	Ministry of Foreign Affairs
MOH	–	Ministry of Health
MOITED	–	Ministry of Industrialization, Trade and Enterprise Development
MOU	–	Memorandum of Understanding
NQCL	–	National Quality Control Laboratories
PEPFAR	–	President's Emergency Plan For Aids Relief
PLHIV	–	People Living With HIV
PMPA	–	Pharmaceutical Manufacturing Plan for Africa
PIC/S	–	Pharmaceutical Inspection Co-operation Scheme
PPB	–	Pharmacy and Poisons Board of Kenya
PPE	–	Personal Protective Equipment
LPP	–	Local Pharmaceutical Production
LM	–	Local Manufacturers
POA	–	Plan of Action
PQ	–	Pre-qualification (regulatory standard of the World Health Organization)
PSM	–	Procurement and Supply Management
QA	–	Quality Assurance
QC	–	Quality Control
R&D	–	Research and Development

TRIPS	–	Trade Related aspects of Intellectual Property
SRA	–	Stringent Regulatory Authorities
SWOT	–	Strengths, Weaknesses, Opportunities, Threats
UHC	–	Universal Health Coverage or Care
UNAIDS	–	The Joint United Nations Programme on HIV and AIDS
UNIDO	–	United Nations Industrial Development Organization
USAID	–	United States Agency for International Development
USD	–	United States Dollar ($)
VAT	–	Value-Added Tax
WHA	–	World Health Assembly
WHO	–	World Health Organization of the United Nations
WTO	–	World Trade Organization

Acknowledgement

The Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) Kenya appreciates Dr Wilberforce O. Wanyanga (Lead consultant) and Justus Ogando (Associate Consultant) for leading the audit and drafting this report. Special appreciation to the KELIN project team led by Timothy Wafula (Ag. Programme Manager, HIV, TB and Key & Affected Populations) and Okania Pesa (Programme Officer, HIV, TB and Key & Affected Populations) for their invaluable support in undertaking this audit.

KELIN acknowledges and appreciate the technical and financial support from Aidsfonds Foundation towards this audit.

Published August 2023.

Executive Summary

This report outlines the findings of an audit commissioned by the Kenya Legal and Ethical Issues Network on HIV and AIDS with technical and financial support from Aidsfonds Foundation. The audit was carried out by a team of consultants led by Dr. Wilberforce O. Wanyanga (lead consultant) and Justus Ogando (Associate Consultant). The report provides a status audit of the state of local production of generic medicines for People Living with HIV-Aids (PLHIV) in Kenya and provides gaps, and policy recommendations.[1]

Anchored under KELIN's project titled Challenging Intellectual Property Barriers that Prevent Access to Treatment for Persons Living with HIV in Kenya, this study sought to understand and verify KELIN's concerns that Kenya still imports 99% of ARVs from outside the country despite the presence of competent local manufacturers. For this reason, there was need to understand the terrain of the key issues affecting Kenya's ability to realize the dream of local ARV manufacturing.

The study was conducted over a period of 30-day between May and July 2023, through a rapid and lean audit. In line with resources available, and due to the sensitivity/confidentiality attributed to information coupled with apathetic local manufacturers of ARVs, a lean number of targeted individual and institutional stakeholders were selected to assist in obtaining pertinent data and information through interviews that would give an indication of the state of local ARV production in Kenya. The criteria for selecting stakeholders reflected diversity within the national HIV-Aids space and geographically.

Anchored under KELIN's project titled "Challenging Intellectual Property Barriers that Prevent Access to Treatment for Persons Living with HIV in Kenya", this report provides a status audit of the state of local production of generic medicines for People Living with HIV-Aids (PLHIV) in Kenya and provides gaps, and policy recommendations.

[1]KELIN terms of reference

The study established some key factors affecting the development of Local ARV manufacturing: -

i. Political Will within Government (inadequate and/or unfulfilled implementation).
ii. Weak Policy, Legislative and Regulatory Frameworks.
iii. Infrastructure, Institutional, Economic and Financial issues.
iv. Appropriate Business model or Value-chain.
v. Human capital development.

Findings from the literature reviewed and the interviews conducted showed there had been relentless and concerted efforts among local manufacturers and CSOs in support of this initiative, but political will has been lacking or lukewarm within Government and its agencies. The Government seems to be working at cross-purposes from a policy, legislative, and regulatory perspective, which continues to make it prohibitive for local manufacturers to participate in a level playing field with importers and foreign manufacturers. Further, economic, value-chain, infrastructure and human resource issues continue to present challenges to the sustainability of the business model.

Initial attempts by Local manufacturers to produce ARV through Voluntary Licensing has grossly been frustrating despite registered products. Voluntary licensing was received from GSK and Boehringer (European manufacturers) but stopped years back. The APIs were sourced from Indian suppliers. Unfortunately, production was not sustainable due to the inconsistency of applying WHO-GMP and WHO-PQ as standards on LM[2] without providing clear protocol guidance and threshold requirements, resulting in Local Manufacturers ceasing ARV production altogether.

The study came up with some recommendations for the way forward, the key of which is a review and overhaul of the policy, regulatory and legislative framework for coherence and strengthening their implementation.

In section 8.0 of this report, detailed recommendations are provided under each of the four major areas with key findings (Political Will, Policy, Regulatory, and Industry Value-Chain or Business Model). However, below a targeted summary of categorised recommendations are proposed:

Recommendations for advocacy purposes:

a) Pro-local policy and implementation

There is an imperative need for Government to align its national and regional policies and strategies related to local production, and to leverage regional economic integration and coordination platforms to support products with sizeable regional demand to expand access to markets and enhance the sustainability of local production. This will ensure the ring-fencing of the "local preference" clause in favour of local products as far as the ARVs' tender process is concerned.

b) To ensure written incentives for LM as a government position is not variable.

Noting that the benefits of LM are clearly enshrined in the 2012 KPSDS and the 2010 National Pharmaceutical Policy, the haphazard and poor implementation of policy and a weak or lacking operative framework must be urgently addressed. In the spirit of nationhood and for Government to be seen to be coherently working for its citizens, a seamless alignment between leadership, policy, strategy, implementation, and accountability, among relevant Government agencies and key stakeholders, will ensure that LM is prioritized and retained as ongoing national agenda of critical importance regardless of a regime change.

To this end, KELIN proposes the development of an agenda by the government during and when negotiations commence to include long-term and sustainable local sources of pharmaceutical products to inject budgetary support locally, and further enhance negotiation for donor support in

[2]Note: LM used interchangeably with LPP

medicines supply to include domestic sources and incremental procurement of the products to avoid funding of competition outside Kenya.

c) To ensure pro-local as bilateral agenda in high-level government

There is an urgent need to strengthen Government leadership, coordination, commitment, and support in promoting the establishment and strengthening of quality and sustainable local production of medicines that follow good manufacturing practices. This will align efforts to address regulatory weaknesses in GMP implementation and ensure that the KPSDS 2012 is fully implemented. Further, there is a need to enhance inter-ministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable. This will help to revive and galvanize past efforts at inter-ministerial coordination (MOD, MOTC, and MOF), strengthen leadership between PPB and MOTC as well as enhance coordination between NQCL and PPB in facilitating quality-assurance of medicines.

d) Formation of national coordination for pro-local agenda

As there is no specific pro-local policy and incentives, the establishment of inter-ministerial coordination alongside strengthening the leadership of PPB and NQCL will help spur R&D for local pharma to produce research-based products. This will minimize the current off-patent generics production pathway and encourage local manufacturers who are disincentivized (by the current private-sector-driven voluntary and compulsory licensing) due to fear of litigation. This will build trust between Local manufacturing and Research institutions through MOUs.

Further afield, national coordination efforts should aim to address inhibitory activities like the existing legislative gaps between VAT zero-rated and Exempt tax regimes as applied between imported and locally produced medicines respectively, and which continue to disincentivize and discourage local manufacturers. Efforts should be made to conduct legislative literacy.

Recommendations to carry forward to the Government:

Key factors were identified, particularly around leadership alignment and commitment to ensure special attention in prioritizing a coordinated implementation of key policy charters that will urgently address the crippling issues in the pharma sector as well as promote incentives and relevant policies stances that are in favour of the development of Local Manufacturing [See section 9.3 for further details]: -

- The 2010 National Pharmaceutical Policy Sessional Paper No.4 (sectoral reformation)
- The 2019 Kenya GMP roadmap (implementation incomplete).
- The Big Four agenda on Manufacturing (to re-prioritize focus on LM)
- The Buy-Kenya-Build-Kenya brand (to catalyze the LM initiative)
- The Constitution, Kenya Vision 2030, and the Kenya Health Policy 2014-2030 (guarantee health as a fundamental human right)
- The supply chain strategy 2020-2025.

A judicious and well-coordinated implementation of the above policies and follow-through of the same will greatly ensure all the moving pieces are geared towards supporting the LM agenda. Consistent and constant advocacy should be maintained along the way to ensure accountability to all stakeholders while securing LM agenda as part of ongoing national conversations regardless of regime change.

Conclusion

The landscape for a sustainable, resilient local production of ARVs in Kenya is not promising at the moment, despite the availability of know-how, skills and lessons learnt from COVID-19 pandemic notwithstanding WHO resolution of 31 May 2021, a 'Strengthening local production of medicines and other health technologies to improve access' as necessary mitigation to supply challenges including stock outs, hitches in supply of APIs that can dent an already existing ART regime. The lives

of PLHIV is largely depended on existing ARV supply value chain currently pegged on 90% imported and donor supported PSM mechanism. This is not sustainable in the event of global changes in the current supply paradigm. It is vital that a pro-local pharmaceutical framework be adopted to support and sustain a local pharmaceutical supply and availability of quality essential medicines including ARVs.

1.0 Introduction

1.1 Background

Access to safe and affordable medicines is critical to the enjoyment of the highest attainable standard of health as guaranteed in the Constitution of Kenya 2010. Access to medicines entails having safe medicines continuously available and affordable at both public and private health facilities including medicine outlets.

Antiretroviral (ARV) medicines have greatly improved lives of People Living with HIV (PLHIV). However, access to ARVs is dependent on their availability, affordability and quality. Local production can fill in this gap and provide benefits including creating a reliable and consistent supply of medicines, facilitating technology transfers, facilitating TRIPS flexibilities, and enhancing self-sufficiency.

It is in this context that KELIN, with support from the Aidsfonds Foundation, under the project titled *Challenging Intellectual Property Barriers that Prevent Access to Treatment for Persons Living with HIV in Kenya* conducted a status audit of the state of local production of generic medicines for PLHIV in Kenya and to develop a report containing the status, gaps, challenges, and policy recommendations.[3]

1.2 Epidemiology Landscape

Despite significant gains in HIV mortality with a 57% reduction in AIDS-related deaths from 52,969 in 2010 to 22,372 in 2022, Kenya still has the world's 6th highest rate of AIDS-related deaths, and 4th in Sub-Saharan Africa. The HIV burden is concentrated in just 15 high-burden counties where 70% of infections occur (HIV Estimates 2022)[4].

Kenya has made great progress towards achieving the UNAIDS 95-95-95 targets and HIV epidemic control. As per 2022 Kenya HIV Estimates, there were 1,437,267 PLHIV, comprising 1,358,277 adults and 78,990 children with a total of 1.29 million patients currently on ART. The Kenya AIDS Strategic Framework (KASF) II, 2021/2022 – 2024/2025 aims to reduce AIDS-related mortality by 50% and new HIV infections by 75% by the year 2025[5]

[3]KELIN terms of reference

[4]Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy, WHO 2018

[5]Kenya Aids Strategic Framework, 2021/22 – 2024/25

1.3 Pharmaceutical Landscape

An overview of the pharmaceutical industry in Kenya shows there are ~37 manufacturers, while the addressable pharma market size is KSh. 273 billion, yielding 20,000 direct and indirect jobs with a potential to grow by 10% year on year. Exports were valued at KSh. 8.4 billion (with EAC accounting for 49%). Kenya imports ~70% of this KSh. 273B addressable pharma market size of which ~60% represents imported generics by quantity. The average revenue generated by every $1 of CAPEX is $ 1.5 billion with a projected sector growth rate is 7% until the year 2027[6].

Assured and consistent supply of much-needed health products of the right quality, quantity, and at the right place is pertinent to ensuring that treatment disruption is contained to the bare minimum. Kenya is at an inflection point in the journey of building a local pharma value chain for sustainable ARVs manufacturing. A slow-paced, rare, and growing combination of political will, trade laws, government, and donor commitment, requisite local skills and knowledge, infrastructure, and other resources may enable maximum value addition for local manufacturers. Additionally, differentiated coordination and collaboration approaches are needed to position local manufacturing and procurement of quality-assured ARVs on the right trajectory – in Kenya and for PLHIV. The successful transition to a robust, sustainable local ARV manufacturing industry that delivers a significant range of products and volumes at required standards of quality and competitive prices will require a framework and approach that translates policy into implementation schemes, expedites change, sustains momentum, is accountable, and maximizes success for all the stakeholders in the pharma sector and HIV care and treatment space.

1.4 Regulatory landscape:

Kenya has regulations and monitoring systems in place, backed by stringent mechanisms of enforcement. These effective regulatory landscapes ensure strict adherence to the Pharmacy and Poisons Board (PPB) regulations, and Good Manufacturing Practices (GMP) and WTO/TRIPS agreement. However, evidence of effective implementation and PPB oversight capacity needs further verification as various reports[9,11,12,14] are indicative of notable weaknesses in their enforcement due to capacity constraints. Moreover, there is no guidance that would create or inspire local industry to take advantage of international agreements such as Doha declarations. It is prudent to note that local investors will not take risks unless the government takes the lead in seeding demand. But since donors were at hand it can be concluded the government did not have interest to pursue the matter.

The Kenya regulatory authority is not listed by the WHO Global Benchmarking Tool (GBT) and seems to suggest urgent need for support program to support and strengthen the regulatory capacity[7,8].

2.0 Purpose

The main purpose of this assignment was to conduct a status audit of the state of local production of antiretroviral (ARV) generic medicines for people living with HIV in Kenya, with the following specific objectives: -

i. To conduct a comprehensive audit of the state of local production of ARV generic medicines for people living with HIV in Kenya.
ii. To develop a research report containing the status, gaps, challenges, and policy recommendations.

3.0 Understanding the Scope

The overall scope of work was to carry out a comprehensive status audit of the state of

[6]Presentation to the FKPM

[7]https://www.bing.com/search?pglt=41&q=WHO+Global+Benchmarking+tool&cvid=e84521f1c1f849a59fefd4bbeacd6e9b&aqs=edge..69i57j0l8.30718j0j1&FORM=ANAB01&PC=LCTS

[8]https://msh.org/resources/the-who-global-benchmarking-tool-a-game-changer-for-strengthening-national-regulatory/

local production of antiretroviral (ARV) generic medicines for people living with HIV in Kenya. It was understood that this broader scope - included:

- "As-Is" audit of the state of local ARV production to identify and document key findings, gaps, and risks from the assessment.
- "To-Be" recommendations of key measures and mitigation strategies to address the gaps and risks identified during the assessment phase.

Within the envisaged assignment timeframe of 30 days, the Consultants understood that this exercise would not be involved in the implementation of proposed recommendations, as that would require extensive institutional stakeholder engagement and cross-sectoral policy changes, which would have to be considered under a separate contract.

The Consultants, therefore, understood that it would be the prerogative of KELIN to determine how the implementation of our recommendations would be done.

This inception report sets out: -

- The approach used in this assessment.
- The key evaluation questions and methodology.
- The information on data sources, collection, sampling, and indicators that were tracked.

4.0 Approach

Given the 30-day timeline for executing this assignment, a rapid and lean audit was recommended. In line with the available resources, KELIN recommended a lean number of targeted institutional stakeholders that would give an indication of the state of local ARV production in Kenya. In this regard and in consensus with the consultancy:

- KELIN provided a listing of, and availed existing, relevant documents within their custody for the consultants' initial desk review.
- KELIN proposed a list of targeted stakeholders for consultants' outreach and agreed the format for outreach (virtual, physical, guided interview, questionnaires etc.); and further, KELIN assisted with contacts of stakeholders and partners they have worked with on this and similar other past projects, while the Consultants also undertook to provide any relevant contacts pertinent to this exercise.

The criteria for selecting stakeholders, though not conclusive, reflected a representative sample indicating:

- Diversity within the national HIV space (MOH, KEMSA, PPB, ARV Manufacturers (Kenya) , select public ART centres and private retail outlets, key PSM funders, Civil Society involved in HIV advocacy)
- Geographically diverse and dispersed facilities. Due to time limitations, the Consultants targeted a few referral facilities located in Nairobi and one outlying county on the fringes of Nairobi metropolis.

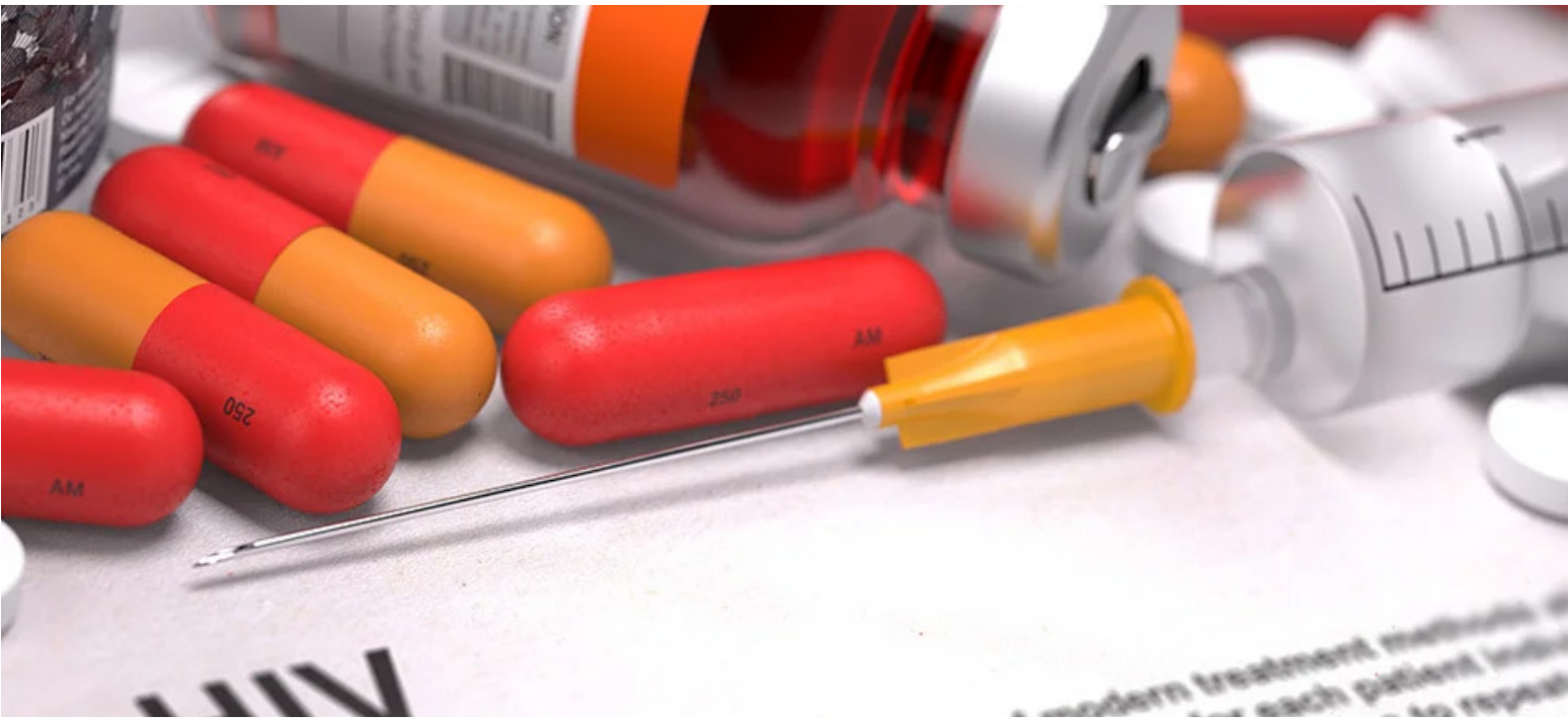
5.0 Deliverables

a) Inception report
b) Draft report on the status audit, highlighting: -

- Key findings identified gaps and risks.
- Annexure of summary from tools and questionnaires.
- Comparative benchmark review to validate findings.

c) Final report containing policy recommendations, highlighting: -

- Executive summary of high-level recommendations
- High-level policy-implication suggestions
- Advocacy statements to promote local manufacturing and procurement.



6.0 Critical Success Factors

The successful delivery of this assessment against the agreed-upon objectives was defined by the depth of analysis of available information and the cooperation of the interviewees from LM of ARV products. In the process two ARV manufacturers were identified. It was agreed that due to the prevailing sensitivity and being current suppliers, the project reporting would be cognizant of the position of local suppliers, noting the deficiencies and weaknesses while remain anonymous about the source. This report is thus silent on the source of the information from LM, while explaining the apprehension on lukewarm policy implementation.

6.1 Dependencies, Considerations, and Assumptions

- The maximum time provided for this study was 30 consultancy days which translated to 1.5-months elapsed period excluding weekends and Kenya government-gazetted public holidays. The Consultants understood these 30 days would be accrued only on a weekday basis. Thus, the project kick-off date was contingent upon receipt of a mutually signed contract and kick-off meeting.
- Project Management Office (virtual and/or physical) was established for seamless coordination, planning, and communication across the matrix for effective information and document-flow control.
- At the initial kick-off meeting, both KELIN and the Consultants agreed on the modality of deploying and administering questionnaires and assessment tools (e.g., E-mail, online Google survey, virtually guided interview, printed physical tools etc). The medium and time taken to administer the tools was outside the Consultant's control and depended on the cooperation and responsiveness of interviewees, and such delays were not construed to accrue as part of the 30-day timeline allowed for this project.
- Identification of key institutional contacts for this audit was mutually agreed upon at the kick-off meeting. KELIN support with identification of key stakeholder contacts for purposes of introducing this project, Consultants and obtain consent.

6.2 Constraints and Risks

Indeed, the anticipated issues surrounding the management changes at PPB and KEMSA and the

subsequent litigation were discussed with KELIN and consensus agreed upon on the way forward. The Policy Brief approach was agreed to protect information sources.

Below are the issues raised in the inception report:

- Delays in communication, responsiveness, and mechanisms for issue resolution during the conduct of this assessment would be mitigated by frequent progress updates.
- Time, availability, and responsiveness of interviewees and adequate resourcing for on-site or remote execution of this assessment (including KELIN staff availability and time)
- Poor or non-responsiveness from interviewees for non-assisted/guided questionnaires and the need for secondary iteration to validate responses and feedback.
- Lack of time to conduct stakeholder sensitization on how to fill questionnaires or data to avoid ambiguity and achieve the SMART principles in the project objectives.
- Interviewees' delay in relaying feedback or providing outdated data feedback.
- Feedback of anecdotal nature in the questionnaires which become difficult to validate.
- Institutional stakeholders' sensitivities (e.g. need for multi-level approvals to avail data)
- Time taken by KELIN to review and sign-off deliverables on acceptable quality standards.
- Potential lack of inclusion of sample HIV+ patients for 360-informed feedback loop on the state of medication quality and adverse reactions to validate quality/ counterfeit concerns.
- Poor responses from interviewees due to fatigue and non-promissory and no tangible returns to manufacturers from similar other previous surveys (usual complain has been "what do we get out of this exercise").
- Potential unforeseen force majeure situation at targeted institutional stakeholders e.g. abrupt changes at KEMSA or other key stakeholders.

7.0 Key Findings

This study sought to verify KELIN's concerns that Kenya still imports 99% of ARVs from outside the country despite the presence of competent local manufacturers in Kenya. So, we need to understand the terrain of the key issues.

7.1 Political Will

- Regionally, the Kenya Government is considered a political leader with democratic governance. Since independence, there has been a transition after every general election. Kenya is a favourite destination acclaiming international and bilateral support, as evidenced by the ARV funding by PEPFAR and USAID (whose budgetary support of over 95%), and recently during the COVID-19 pandemic with donations worth several millions of USD including vaccines and PPEs.
- During the development of the support arrangements, support for local manufacturing as a local source of critical medicines did not appear penned down. The *WHA74.6 Strengthening local production of medicines and other health technologies to improve access* was articulated in view of the challenges facing medicines availability. This is in view of the benefits for Local production to improve access to quality affordable medicines i.e., reducing dependency on imports and strengthening national health security, catalyzing local capacity for innovation, strengthening health personnel capacity, and stimulating knowledge-based economy and social development to save forex, create jobs, facilitate technology transfer and stimulate exports.
- In recent years, there has been a lot more advocacy traction by both KAM and FKPM at the Executive level of Government in support of local manufacturing but these efforts have not translated into catalysing a positive flywheel and progress is partial.
- Since the tenets of donor funding are based on access and availability of affordable

quality medicines it is surprising that the donor support agreements are silent on local sustainable sources of supply and hence the need for a high-level agenda to pursue the development of sustainable local production. FY2022/23 – FY2024/25 ARV quantification data indicated that Kenya's ambitious optimization agenda towards the UNAIDS 95:95:95 target resulted in the most Adult and Peds patients on a few predominant 1st Line and 2nd Line ART regimens. Out of nine (9) ARVs that would qualify for Local Manufacturing consideration (*due to economies of scale availed by the sheer patient numbers),* the Government only funds PSM for 4 ARVs but corresponding volumes are paltry, and tenders are still awarded to foreign importers. PSM for all nine (9) ARVs is predominantly funded by PEPFAR and GF. (See Annex 1: Tables 3 and 4)

7.2 Policy

The Kenya National Pharmaceutical Sector Strategic Plan (2012) with assistance of UNIDO, identified seven strategic areas to support local manufacturing, and these included the following:

i. Setting out a roadmap for the industry to achieve GMP Standards
ii. Strengthening mechanisms for quality assurance of medicines in the distribution chain
iii. Strengthening regulatory capacity
iv. Accessing necessary financing for investment in the sector
v. Devising time-limited incentives for industry
vi. Developing necessary human resources
vii. Developing common support services for the local pharma industry

- An implementation plan was developed for the first area through the development of the Kenya GMP Roadmap (2014-2019) and lately activities have started on strengthening the Regulatory Capacity. There was notable improvement to the GMP performance and liaison with PPB through regular meetings. However, local manufacturers still face unpredictable policy shifts compared to other sectors. Through FKPM, local manufacturers continue to lobby on issues of unfair competition due to inadequate development of incentives, user-friendly financing options, and human resource development with skills and know-how relevant to manufacturing.
- Despite FKPM developing and submitting a policy paper to the Government, execution, and implementation remains the weakest link on the Government side. The Policy paper defined incentives Government could extend to local manufacturers. However, successive Governments have continued to form Taskforces to see its implementation, but this never saw the light of day. Some level of seriousness is clearly needed for the country to adapt working models (e.g. India, Bangladesh) and apply them at locally.
- Legislative members could benefit from literacy about the sector-specific nuances around regulatory and tax laws especially pharmaceutical matters, considered quite complex. Existing literacy gaps discourage local manufacturers *e.g. there is limited understanding of the difference between Zero-rated and Exempt products and on a technical level the difference between WHO GMP and WHO PQ.* ARVs are exempted and not Zero-rated. In a Zero-rated regime, a manufacturer can claim back VAT and input tax but in an Exempt regime, this is not possible. An exempt regime discourages local manufacturers who opt for importation an easy way out to reduce operating costs and shore up working capital. If they were to locally produce, the Exempt status of pharma products does not allow them to recoup input tax and VAT. On the other hand, WHO GMP is a basic requirement and WHO PQ is voluntary and product-based, and Expression of Interest from Manufacturers of ARVs, Anti-Malarial mainly favour foreign manufacturers who enjoy economies of scale since local manufacturers require an upfront capital investment of over USD 10 million (excluding the cost of purchasing land) to set up an average manufacturing plant.

- KEMSA tender process is governed by the Public Procurement Act (PPA) which discourages Local Manufacturers as it stipulates that locals are to be automatically allocated 15% value of any tender and 10% for importers. The 5% differential local manufacturers are presumed to gain over importers is hugely undone by the high cost of production and limited incentives in laws as well as opportunity costs foregone by not being able to claim input tax and VAT on Tax Exempt products. Thus, there is no incentive for Local importers to bear the cost of putting up a specialized greenfield production line of at least USD 10 million to carry out local manufacturing.

7.3 Regulatory

- Kenya is yet to find space on the WHO Global list of Benchmarking Pharmaceutical Regulatory Authorities. In EAC only Tanzania is listed on List of National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3)1 and maturity level 4 (ML4)2 (as benchmarked against WHO Global Benchmarking Tool (GBT)[9]. According to WHO there are fewer than 30% of regulatory authorities in the world who meet the criteria of performance of maturity level. The most current status is not available due to planned WHO assessments this year.
- Kenya's self-sufficiency in local manufacturing has been a motivation since the 2000s when the first-ever voluntary license was granted to a local manufacturer to produce and register at PPB an ARV with APIs imported from an Indian generic ARV manufacturer. In 2004, European innovators – *GlaxoSmithKline (GSK) and Boehringer Ingelheim* – granted voluntary licenses to local Kenyan manufacturer. However, executing production became problematic as the formular was changed by MOH/WHO and procurement was done to fill gaps of supply rather that a planned annual quantity for economies of scale. Attempts to execute voluntary license in partnership from GSK and Boehringer saw the local manufacturer supply Kenya with this ARV only twice before stopping its production.
- Some of the reasons cited were limited policy and regulatory motivation to stay the course of local ARV production, mainly due to inconsistent application of WHO-PQ standards when it comes to African producers in the pharmaceutical sector. Despite five (5) repeated WHO inspections, the local operations were deemed not to meet the threshold for continuing local ARV production. On the other hand, the same manufacturer continued to supply KEMSA with other products on the basis of GMP adherence. This notwithstanding, other reasons include inadequate technical support and guidance from WHO and a lack of technical expertise from local regulatory authorities. The threshold for meeting WHO PQ requirements are high, expensive and not well coordinated in Government between policy, regulatory, and manufacturing activities. This is evident by the fact that, in the past 10 years, fewer than 5 plants in Africa have successfully met the PQ threshold.
- Though Kenya's GMP standards were better developed than other regions, the inconsistent application of WHO-PQ standards showed that support for promoting local manufacturing is inadequate as there was no proper protocol to achieve the PQ threshold. However, UNIDO global projects to support local manufacturers came in handy between 2005 -2019.
- In spite of EAC's common protocol, the relationship between individual member states is still shaky, unpredictable, or uneasy and cannot guarantee stability and assurances to harness common strengths across borders e.g. *Uganda is unable to sell to, buy from, Kenya despite harmonization efforts of technical matters like registration of products and GMP inspections, because trade-related issues such as tariffs are too stringent for products from Kenya, making them more uncompetitive.*

[9]https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/list-of-nras-operating-at-ml3-and-ml4.v2.pdf?sfvrsn=ee93064f_10&download=true

- Advantages of local manufacturers as a domestic source include nearness for GMP inspections and enforcement. However, there are no laws to empower Kenyan inspectors to enforce inspection findings on companies whose origin outside of Kenya, which is disadvantageous to local manufacturers since quality requirements cannot be equally monitored and enforced.
- Moreover, the sovereignty of export countries does not allow GMP inspectors from Kenya to enforce the findings of the inspection, which is a major weakness in the execution of inspection laws and capacity to execute mandate at the products' origin outside Kenya and apply the same standards at the destination (within Kenya)
- The regulatory, oversight, and supervisory capacity of the Pharmacy Poisons Board (PPB) of Kenya is constrained, making it very difficult to restrain sub-standard and counterfeit drugs still infiltrating the local Kenyan market (e.g. from the Far East countries)
- Local regulator has also been made aware that pre-packaging is not a long-term solution to health security. Manufacturing process would engage the design of a facility, product selection, formulation, processing, and quality control into Finished pharmaceutical product. The packaging is the "end-of-the-stick" from another manufacturer. Facility requirement and investment is yet another disadvantage to genuine local manufacturers and packaging facilities will import bulk products and packaging materials. There are no policy guidelines to protect full-scale investments in local production against bulk products. This notion is discouraged as it will short-circuit genuine LM who have invested heavily in full production.
- Further as stated above, the Kenya regulatory Authority has no powers to enforce GMP over a company domiciled outside Kenya to ensure safety, quality of FPP. Also, the bulk unfinished products cannot be a registered product given that there is no law to control both starting and raw materials in Kenya. This offers a risk for importation of bulk and package counterfeits and sub standards.

7.4 Industry Value-Chain and Business Model

- The combination Medicinal and Pharmaceutical Product Exports[10][CITATION KNB \l 1033] increased from 108.1 to 119.8 (11.9%). This shows an upward growth except the volume of output in the manufacturing sector expanded by 3.8 per cent in 2022 from a growth of 6.5 per cent in 2021. This indicates a recovery from COVID pandemic and local procurement when imports were less. The depression started 2020/2021 improved fem 2021. This data indicated that Import dependence is very risky.

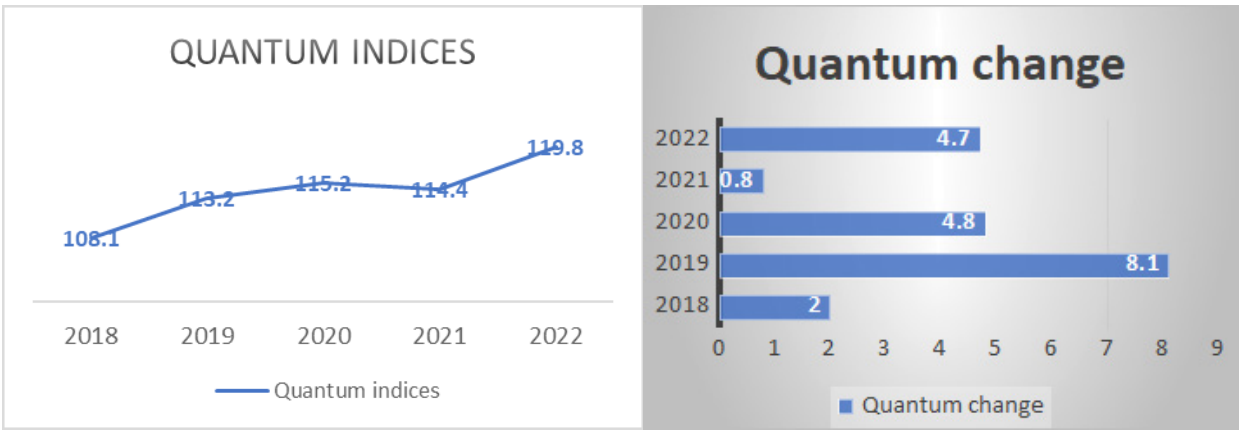


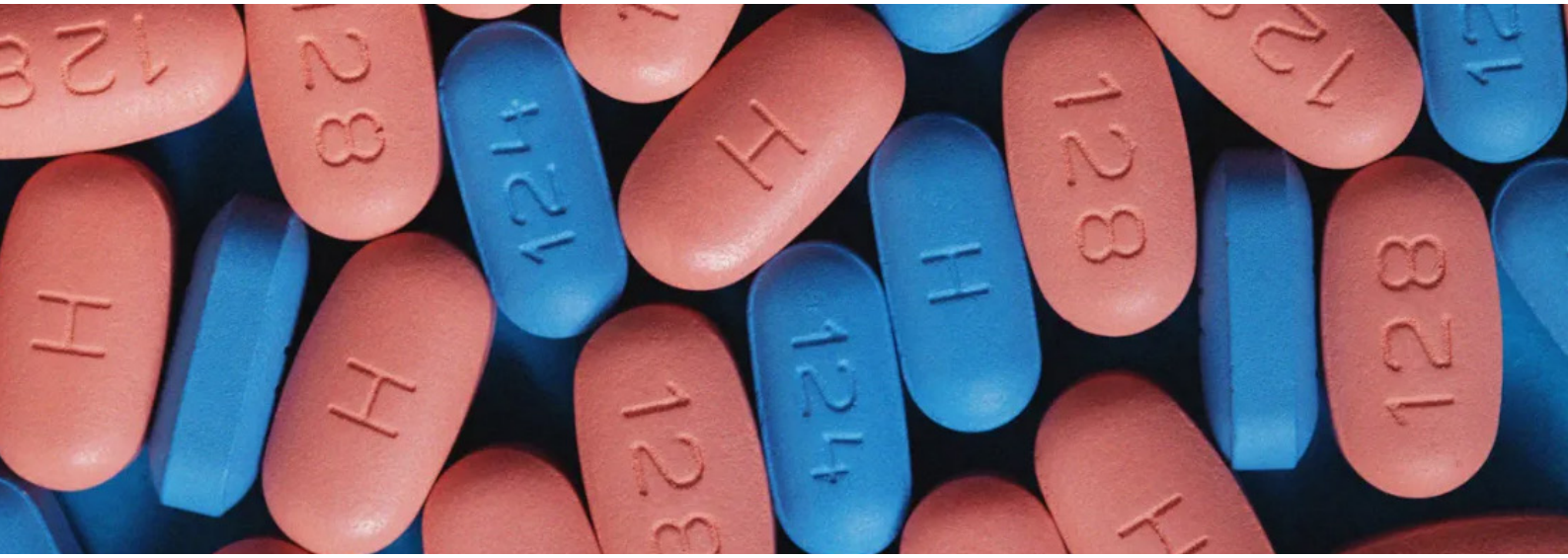
Figure 1: LPP Quantum Manufacturing Indices & Change Source 1: Economic Survey 2023, KNBS

[10]Economic Survey 2023, KNBS

- The combination Medicinal and Pharmaceutical Product Exports[10][CITATION KNB \l 1033] increased from 108.1 to 119.8 (11.9%). This shows an upward growth except the volume of output in the manufacturing sector expanded by 3.8 per cent in 2022 from a growth of 6.5 per cent in 2021. This indicates a recovery from COVID pandemic and local procurement when imports were less. The depression started 2020/2021 improved fem 2021. This data indicated that Import dependence is very risky.
- Only 1 of 37 local manufacturers modelled its business around (WHO-PQ -donor-funded tenders, but the rest are modelled around commercial and private sector markets. But regardless of the WHO – PQ status of any of the 37 local manufacturers, the business model for local manufacturing is not sustainable without vertically integrating with API manufacturers because the volumes are small, but value-chain costs are high. All local manufacturers of ARVs import APIs from India and China generic suppliers who are as well competitors in local tenders. Unless the local business model integrates the APIs sources into their value chains, the small volumes, lead times, markups, costs etc, adversely affect local manufacturers.
- Unfortunately, the current regulatory and value-chain model may not make it possible to produce APIs in Kenya as the chemical processes and licensing are complex and without supportive policy and regulatory development. The botanicals from plants that do thrive in this region are processed and exported as crude medicines (artemisia for treatment of malaria) and later imported expensively as APIs. The only available option is synthetic APIs which are challenging, complex, and costly to carry out from an extractive perspective. Kenya could leverage attracting multinationals to bring in and/or transfer technology to local manufacturers.
- India established a policy that closed their domestic API market to multinationals and only allowed multinationals to enter joint-venture (JV) arrangements with local India generic manufacturers to lock down multinationals and ensure knowledge incubation and transfer of technology. This is the same model adopted by the Moroccan and Tunisian Governments.
-
- Economies of scale do not favour the level of effort required to service KEMSA contracts as volumes are small (KEMSA accounts for 20% of total business for some local manufacturers), while simultaneously local businesses have to fight and control counterfeits and substandard products from decimating available market share and businesses reputation due to quality concern.

7.5 Human Resource Development

- Kenya is endowed with one of the most intellectually adept and progressive populations in Africa and the Government should be seen to work for its citizenry by making every effort to harness this resource and avoid a flight of intellectual capital to other countries.
- There is limited industry-skill for pharma development. There are over five schools of Pharmacy in Kenya, but the curriculum is more clinical oriented. The exposure of pre-employment workforce is limited to three months internship program inadequate to re-orient and equip potential employees with technical knowledge and skills. On the flip side, graduates from India have better exposure in pharmaceutical training. Much as they are prime for employment, their work permits allow limited stay and as such not sustainable. Unfortunately, the policy interventions have been silent on building a sustainable capacity-building program in Kenya.



8.0 Critical Success Factors

The conduct of this study was premised on a SWOT analysis, policy and literature reviews, and interviews with stakeholders in the pharmaceutical sector. Some of the notable Pro-Local Policy stances and narratives are summarised in the table below: -

8.1 General Pro-Local Policies

Table 1: Summary of Pro-local policies

Pro-LPP Policy

- Pro- Local Implementation
- Agreements and MOUs
- List Pool items - Slow moving
- List of Direct Deliveries - LM
- Local Preference
- Payments

Quality & Standards

- Local Prequalified
- Pre-Qualified
- Products Local
- GMP and GWP Inspections Approved QC laboratory(ies)
- Certificate of Compliance

Pro-LPP Cordination

- Feedback Reports
- Deliveries
- Stock levels
- Stockouts
- Payments
- Quality

Pharma Regulatory

- GMP
- GWP
- Procurement procedures
- Quality Control – sampling and reporting

Pharma LM

- Manufacture
- QA
- Deliver
- Distribute
- Local Preference

Warehousing

- Stock levels
- Re-Order Levels
- Expiry Control
- Pool Items
- Direct Delivery by LM

9.0 Specific Pro-Local Policies Narratives

9.1 International

a) PMPA Business Plan 2012[11]:

This was an initiative of the Africa Union with support from UNIDO. Its focus was to promote access to quality and affordable medicines by integrating local manufacturing into the health systems. It received the highest continental approval from the Assembly of Heads of State and Governments in Addis Ababa. The purpose was to establish Africa's local pharmaceutical production capacity, build the strategic partnerships required, and engage governments in the development of business and operational business plans.

The need arose from the fact that Africa faced the biggest burden of diseases (i.e., HIV at the time) yet Africa faced negative issues to do with access, availability, and poor standards of products. The market was predominantly import-oriented, and both local manufacturing facilities and regulatory authorities lacked the requisite capacity in terms of infrastructure, human resources, and technical capacity to develop and sustain international standards. Though activities are ongoing at the continental level, the translation to regional, national, and facility level lack the necessary drivers like pro-local policies, strategies and implementation plans.

b) WHA resolution:

At the onset of the COVID-19, pandemic the WHA convened a meeting to consider the preparedness of countries in response to health emergencies. This was in the context of an earlier call on the fundamental right of everyone to attain the highest possible level of health. The building blocks included: -

- Voluntary transfer of technology and know-how on mutually agreed terms; and
- Development and local production.

Given that Kenya, like other countries, had initiated Local manufacturing initiatives, there is no progressive policy implementation for realizing this goal.

c) WHO Policy Brief on Local Production - Local Production for Access to Medical Products Developing a Framework to Improve Public Health.

The WHO brief underscores the need for a coherent long-term policy approach with the understanding that implementation should take into account product acceptability and affordability, local manufacturing improves access, and the existence of international and national initiatives including trade.

However, there could be health and industrial policy incoherence to be harmonized to ensure a strong linkage between local manufacturing and access. The focus is to support local manufacturing for improving access and the recognition that local manufacturing contributes to economic development while simultaneously meeting healthcare needs.

9.2 Regional

d) EAC Regional Pharmaceutical Manufacturing POA 2012 -2027[12]:

This report is founded on the premise that the EAC region can build up an efficient pharmaceutical industry to supply the market with efficacious quality medicines to resolve insufficiencies of supply (availability) and access. It contains a framework for putting up a GMP roadmap for local manufacturers to attain international standards; develop a platform for sustainable access; formulate and implement and promote policy coherence amongst other factors and incentives for the manufacturers and R&D. It has a ten-year window for implementation. In comparison to Kenya's GMP program which was initiated from 2014 – 2019, there is a lag period that would appear that the incoherence in the period was not addressed. As such, a Kenyan manufacturer's

[11]Pharmaceutical manufacturing Plan for Africa, Business Plan , AUC-UNIDO

[12]2nd EAC Regional Pharmaceutical Manufacturing Plan 2017-2027

initial lead did not offer an advantage since there is a waiting period of more than 8 years except for individual manufacturers' efforts.

9.3 National

e) Sessional Paper No 4 on National Pharmaceutical Policy June 2010[13]:

The Kenya National Pharmaceutical Policy (KNPP) succeeds the Kenya National Drug Policy (KNDP) of 1994 was the forerunner to Sessional paper 4. This was developed as a blueprint for reformation of the pharmaceutical sector 'to ensure equitable access to Essential Medicines and essential health technologies for all Kenyans'. The policy paper recognized that pharmaceutical sector is a distinct economic entity, with multi-dimensional aspects that have a direct impact on the health and safety of the population, as well as on the national economy, international trade, and cooperation. It required special attention, but implementation remained weak, lacked prioritization, and failed to address emerging issues in the sector including stock-outs, high prices, control counterfeits and substandard among others. in effect the policy document was emphatic that the pharmaceutical sector lacked policies and incentives to drive the development and promote local manufacturing. As a result of the issues, the recommendation was to promote self-sufficiency concept in prediction and eventual export, to be achieved through several objectives including creating of an enabling environment for investments in LM and compliance with GMP standards, transfer of technology, develop incentives, review of laws, enhance and promote procurement, develop incentives and curbing of sub standards and counterfeits and illegal outlets.

Again, such a rich policy document was not enshrined and an implantation program to quantify the success of some aspects. Indeed, it led to reforms in procurement and growth in LM. The UNIDO program came in timely to further strengthen but focused on the technical aspects of the LM.

f) Kenya Pharmaceutical Sector Development Plan, 2012 (KPSDS)[14] and Kenya GMP[15] Roadmap:

This strategy document, published in 2012, has seven strategic components: -

i. Setting out a roadmap for the industry to achieve GMP Standards.
ii. Strengthening mechanisms for QA of medicines in the distribution chain.
iii. Strengthening regulatory capacity.
iv. Accessing necessary financing for investment in the sector.
v. Devising time-limited incentives for the industry.
vi. Developing necessary human resources.
vii. Developing common support services for the local pharma industry.

Of the seven strategic components, there was good progress on developing a Kenya GMP roadmap, but the implementation was unfinished in 2019 because UNIDO funding ended. The Kenya GMP Roadmap is the back-borne for the EAC Regional Pharmaceutical Plan of Action and now used as the basis to develop similar initiatives in West Africa and SADC region.

Unfortunately, there was no strategic breather to continue with the implementation. The inter-ministerial coordinating committees did not address both the administrative and technical hitches in coordination between the stakeholders, MOH, PPB, NQCL, and MOITDC industry. Opportunities still linger since Local manufacturing has been raised repeatedly and is still an ongoing agenda. This means the issue of local manufacturing, implementation of strategies, and policy alignment are incoherent to date.

G) Big Four Agenda[16]:

The Big Four agenda, designed as a transformative agenda and economic blueprint, was introduced in 2017 but implemented between 2018-2022.

[13]Sessional paper No 4 on National pharmaceutical Policy 2010

[14]Kenya Pharmaceutical Sector Development Plan, Kenya/UNIDO project

[15]Kenya Good Manufacturing Practices Road map 2014, Kenya/UNIDO project

[16]Second Progress Report On Implementation Of The Big Four Agenda 2019/2020 -The Big Four Agenda

It was developed by the Government of Kenya with priorities on Food Security and Nutrition; Universal Health Coverage; Affordable Housing and Manufacturing. The UHC agenda would foster quality, promotive, preventive, curative, and rehabilitative health services to ensure individuals and communities in Kenya have access to quality essential health services (including Essential medicines as a key aspect in UHC and Local pharmaceutical production.

In between, the COVID-19 pandemic disrupted major value chains in the Health and Manufacturing Sectors. The disruption was enormous as Kenya experienced stockouts, price increases of medical commodities, and longer lead times. The missed opportunity accelerated the implementation of the existing local initiatives foreseen earlier in the KPSDS and Kenya GMP roadmap.

h) Buy Kenya Build Kenya Strategy:

Buy Kenya-Build Kenya was to ensure and encourage the consumption of locally produced goods and services. In 2015, the President announced that government agencies should reserve 40% of their procurement access to purchase locally manufactured products in order to improve preferential local products and enhance their competitiveness, create synergy to build a strong industrial base, and enhance consumption. Local manufacturing faced challenges because KEMSA tenders were open to international competition. Donor-funded programs, some with more than 85% funding, had stringent measures that locked out local manufacturing. Local preference for the domestic industry was 15% and Kenyan-owned companies 10%, which left the industry with 5% margins since a window was created for imports through the latter category.

10. Advantage of Local Manufacturing

The operative framework is still weak or lacking. The KPSDS is clear on the advantages of local manufacturing, but the haphazard implementation of policies favour imports through the tender system and put much pressure on expanded Quality requirements above standard WHO GMP which excludes local pharma from their growth potential.

Local Production of Pharmaceuticals (LPP) can reduce import dependence and related problems of regulatory load and access, and establish a National Medicines Security that is less dependent on Imports and donors, more responsive to emergencies and provides self-sufficiency espoused on the sessional Paper on National Pharmaceutical Policy of 2010.

i. Provide economic benefits such as job creation.
ii. Up-grade and Build Capacity through know-how and skills training to nationals.
iii. Reduce expenditure of foreign exchange on imported medicines
iv. Open new markets and exports of pharmaceuticals
v. Improve access and quality on the market.
vi. Strengthen and promote more cost-effective regulatory oversight - easier for a local regulator to carry out regular GMP inspections.
vii. Improve traceability of products by strengthening Post-Marketing Surveillance
viii. Shorter lead times and more reliable supplies of medicines improved access for consumers.
ix. Offer protection against interruptions in supply during emergencies and possible continuation of donor funding.

11. Implementation of WHA74.7

Strengthening WHO preparedness for and response to health emergencies, 31 May 2021

Table 2: Pro-local policies supportive of the local manufacturing

No.	WHA requirements	Comment on current status
1.	To strengthen their leadership, commitment and support in promoting the establishment and strengthening of quality and sustainable local production of medicines and other health technologies that follow good manufacturing practices;	Commitment is not marched with efforts. • The KPSDS is not fully implemented. • Weakness in Regulatory in GMP Implementation
2.	To align their national and regional policies and strategies related to local production, and to leverage regional economic integration and coordination platforms to support products with sizeable regional demand to expand access to markets and enhance the sustainability of local production;	Yes. The Local preference for local products is not adhered in regard to ARVs
3.	To develop evidence-based holistic national and regional policies, financing mechanisms, strategies, and plans of action, and to explore appropriate mechanisms to support the sustainable implementation of national / regional strategies for local production in collaboration with stakeholders for strengthening the local production of quality, safe, effective, and affordable medicines, and other health technologies;	• No financing, each company on its own struggle and no evidence of financing mechanisms. Moreover, payment after deliveries delayed for over 6 – 12 months • Pool procurement is a far story
4.	To enhance inter-ministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable;	• Efforts for inter-ministerial coordination (MOD, MOTC and MOF) has not been fruitful • Coordination between PPB and MOTC is weak. • NQCL and PPB failed to provide leadership and facilitation of quality-assured drugs

No.	WHA requirements	Comment on current status
5.	To apply a holistic approach in strengthening local production by considering, for example, promoting research and development, transparency of markets for medicines and other health technologies, regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology transfer on voluntary and mutually agreed terms for production and needs-based innovation, the aggregation of national and regional demand, and appropriate incentives for private-sector investment, particularly in the context of achieving UHC;	• There is no coordination for Local pharma to produce research-based products. • Local manufacturers essentially doing off-patent generics. • Pursuance to voluntary and compulsory licensing purely private sector and low interest due to fear of litigations • No specific pro-local policy and incentives. In fact, some activities are inhibitory for example VAT zero-rated and zero exemption. • Trust between Local manufacturing & Research institutions through MOUs have not been developed (e.g. GOK went alone on EOI for vaccine production, without LMs)
6.	To engage in global, regional & subregional networks related to promoting sustainable local production of quality, safe, effective, and affordable medicines, and to further enhance multistakeholder collaboration;	• Initiatives not fruitful due to selection of items and requirements for WHO PQ without the option of WHO Compliance from the joint inspections.
7.	To further engage in North–South and South–South development cooperation, partnerships and networks to build and improve the transfer of technology related to health innovation on voluntary and mutually agreed terms and in line with their international obligations;	• Nil efforts
8.	To take into account the rights and obligations in the Agreement on Trade-Relate Medicines of Intellectual Property Rights (TRIPS Agreement), including those affirmed by the Doha Declaration on TRIPS Agreement and Public Health, in order to promote access to medicines and other health technologies for all;	• Tenders are open to global competition and do not have option for local bidders as preference because there is no policy • LM compete with raw materials suppliers who have advantage for lower cost • International Tender provisions require WHO PQ on common generics. This negates interest in innovator products • Change in treatment by WHO/GOK regime (2005)[17'18'19] disadvantaged LM as registered

[17]GSK grants 4th voluntary licence for manufacture, sale of HIV drugs in Africa (pharmabiz.com)

[18]https://images.journals.lww.com/aidsonline/Original.00002030-201206190-00012.T1-12.jpeg

[19]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4193472/table/T1/?report=objectonly

product was not required and faced investment to re-start process for the newer regimens and uncertainties for the next change (Annex 2)

11.1 Advocacy Required to Advance Local Manufacturing

a) Fast-track Amalgamation of pro-local pharmaceutical manufacturing initiatives into a government policy which should be implementable at all levels including: -

- Pharma regulation to list companies complying with GMP and suitable preferences
- Inclusion as agenda in international and bilateral talks to support the health sector provide a certain percentage for local procurement on an incremental basis based on quality and capacity.

b) Procurement should give priority and preference to local pharmaceutical manufacturers. -

- Local tenders should specify local incorporation of a site for full manufacture from formulation to Pharma finished products.
- Local manufacturing with arrangements for technical transfer and personnel training should be considered if there are plans are demonstrated for full transfer within a two-year period.
- International tenders should be the products not manufactured locally and/or where capacity building is required.

c) Establishment of a National Pro-Local Coordination Committee with essential reporting mechanism for: -

- Product availability and performance
- Prompt Payments to local manufacturers
- Itemize fast moving products for direct delivery to health facilities
- Itemize products for bulk storage (mainly slow moving)

12.0 Key Recommendations

The operative framework is still weak or lacking. The KPSDS is clear on the advantages of local manufacturing, but the haphazard implementation of policies favour imports through the tender system and put much pressure on expanded Quality requirements above standard WHO GMP which excludes local pharma from their growth potential.

The recommendations have been divided in three thematic areas. However, taking cognisance of the fact that pharmaceutical sector is multisectoral and cuts access the politico-social economic spheres, inclusivity during formulation, implementation is vital. These recommendations are not in any way isolated as a preserve for any sector in ensuring local pharmaceutical sector an focal point in access to quality pharmaceutical products.

A. Recommendations to target Government and/or Donor Agencies:

i) Political will and High Government support

a. Develop a lobbying agenda by the government during and when negotiations commence to include long-term and sustainable local sources of pharmaceutical products to inject budgetary support locally. Such support has a multiplier effect on the economy through taxation, employment, export market, human resource development, and infrastructure.

b. Additionally, high-level policy and political will should be envisaged for sustainable sector development encompassing commercial and private sector inclusivity. Negotiation for donor support in medicines supply should include domestic sources and incremental procurement of the products to avoid funding of competition outside Kenya.

c. When the Ministry of Foreign Affairs (MOFA) develops the agenda for Trade Missions, could this be another entry point for GoK policy to promote local production? But this does not reach the negotiation table for local procurement. However, this is not transparent and above board for factors that cannot be listed in this study.

ii) Policy related

a. There needs to be a defined scheme to upgrade or develop Local Manufacturing to participate in the ARVs tender and market as local manufacturers are grossly disadvantaged to supply ARVs, and WHO does not provide them with the required technical support. It is noteworthy that the inconsistent application of WHO PQ was the likely genesis of the failure of Local Manufacturing. Since WHO PQ is dependent on WHO initiative and compliance listed on the WHO website, local manufacturers who meet WHO GMP requirements upon inspection by the domestic GMP inspectorate are not similarly listed and hence not recognized in ARV tender and supply even though they are licensed, and the products registered.
b. For transparency, incentivization and support for Local manufacturing should be a written public document and de-linked from the Legislative and policy-making process.

iii) Regulatory environment related:

a. The fight and control of counterfeits and substandard is based on domestic policies and the continuous availability of affordable products. It is highly recommended that the development of such policies should in essence leverage local production.
b. Address counter-productive gaps and inconsistencies in the Govt. Finance Act and Tax legislation that are currently working at cross purposes with the Govt. agenda in support of promoting Local Manufacturing.
c. Pharma sector Legislative literacy workshops with FKPM could create enlightenment in tax reforms and address the huge interpretation gaps at the Legislature level.

B. Industry Value-Chain and Business Model :

a. Review Public procurement, warehousing, and delivery system to encourage more direct supply while minimizing delays in payment procedures. Allowing local manufacturers to supply directly to facilities has multiple gains as it is faster, cost-effective, and ensures a quick turn of finances for re-investment and avoiding dead stocks. Further, it leads to the development of a quality-assured, supply system including strengthening of the regulatory system.
b. LPP have a big potential for resilience and hence demonstrates the ability for self-sufficiency and exports to earn the much needed forex
c. Need to change KEMSA's processes and terms of contracting to make it efficient and able to execute its mandate succinctly. KEMSA canceling already awarded contracts or issuing delayed LPOs months after contracting is a damper to any manufacturer's planning. cancelling tenders abruptly also affects GMP and operations for LMs. A mechanism is needed for a holistic view of all value-chain components to be coordinated to work together to avoid such disruptions.
d. Private sector model is on reducing wastage and expiries and KPIs form a critical foundation for excellence in performance standards e.g., inventory holding days, out-of-stock days, and value of expiry in any year can affect performance bonuses. These are reviewed regularly within the private sector (LMs) and it is recommended to adapt these within the public procurement.
e. Timely payments by KEMSA to avoid tying up manufacturers' capital.
f. Based on a balance between cost-effectiveness and efficiency, the current

business for LMs is a non-viable and sub-optimal model and does not motivate the development of local enterprises. The establishment of a viable and sustainable financing model in support of LM development would be a novel idea.

C. Recommendations to target CSO

a. Need to catalyze a positive flywheel that rationalizes and balances the inclusion of the right people within the Government to drive Local Manufacturing decisions, with the ability for Executive monitoring of momentum for accountability, and institution capacity enhancement to deliver on their mandates effectively.
b. Have the right people in Government to be entrusted to drive pro-local sector-specific agenda and decisions supportive of local manufacturing and ring-fencing it within the Executive office to secure efforts as the population's health is both a national security and an economic risk not to be handled loosely (e.g., Digital and Climate initiatives are ring-fenced within Presidency). Otherwise, local manufacturing will just continue to be a Taskforce discussion agenda if the Executive Office does not embed it alongside Public Health as a National Security issue.
c. Formation of national coordination for forum to regularly monitor and the development and progress of multisectoral pro-local pharmaceutical agenda.
d. FKPM should continue advocacy by directly engaging national stakeholders across the board in seeking pro-local pharmaceutical agenda.

13.0 Conclusion

The landscape for a sustainable, resilient local production of ARVs in Kenya is not promising at the moment, despite the availability of know-how, skills and lessons learnt from COVID-19 pandemic notwithstanding WHO resolution of 31 May 2021, a 'Strengthening local production of medicines and other health technologies to improve access' as necessary mitigation to supply challenges including stock outs, hitches in supply of APIs that can dent an already existing ART regime. The lives of PLHIV is largely depended on existing ARV supply value chain currently pegged on 90% imported and donor supported PSM mechanism. This is not sustainable in the event of global changes in the current supply paradigm. It is vital that a pro-local pharmaceutical framework be adopted to support and sustain a local pharmaceutical supply and availability of quality essential medicines including ARVs.

Annex – 1:
ARVs procurement, funding and Regimen evolution and use

Table 3: Annual ARV shipments by Funder and Corresponding PLHIV on each medicine

KEMSA - Annual ARV Shipments (No. of Packs)	June-2021	FY 2021-2022	FY 2022-2023	FY 2023-2024	FY 2024-2025	ART patients on this ARVs		
						Male	Female	Total
Tenofovir/Lamivudine/Dolutegravir (90 tablets pack)								
Consumption (actual issue at the end of each period)	467,177	4,619,378	4,144,750	4,720,092	4,801,800			
PEPFAR shipments		3,062,469	1,734,594	2,100,000	770,741			
Global Fund shipments	499,400	2,703,625	2,548,094	3,272,705	-			
Treasury CPF shipments		481,626	643,801	480,023	-			
MOH shipments		9,301	207,514	-	-			
Tenofovir/Lamivudine/Dolutegravir (30 tablets pack)						359,464	687,354	1,046,818
Consumption (actual issue at the end of each period)		1,681	114,718	496,629	502,896			
PEPFAR shipments		-	-	-	-			
Global Fund shipments		-	-	300,000	-			
Treasury CPF shipments		-	-	684,944	-			
MOH shipments		213,000	-	-	-			
Tenofovir/Lamivudine/Efavirenz (30 tablets pack)								
Consumption (KHIS-reported at the end of the period)		52,765	16,209	40,809	41,328			
PEPFAR shipments		-	-	-	-			
Global Fund shipments		-	-	-	-			
Treasury CPF shipments		-	-	-	-	511	1,418	1,929
MOH shipments		-	100,000	89,100	-			
Abacavir/Lamivudine FDC (600mg/300mg) Tablets								
Consumption (actual issue at the end of each period)	27,124	297,942	348,867	297,024	306,828			
PEPFAR shipments		137,690	-	-	-			
Global Fund shipments	149,819	123,200	588,987	246,499	-			
Treasury CPF shipments		-	-	-	-	5,076	7,215	12,291
MOH shipments		-	-	-	-			
Tenofovir/Lamivudine FDC (300/300mg) Tablets								
Consumption (actual issue at the end of each period)	72,407	667,410	599,550	485,700	450,204			
PEPFAR shipments		349,192	405,698	-	-			
Global Fund shipments		-	-	750,000	-			
Treasury CPF shipments		-	-	240,000	-	13,529	27,365	40,894
MOH shipments		-	87,645	-	-			
Zidovudine/Lamivudine FDC (300/150mg) Tablets								
Consumption	49,847	528,369	444,238	489,156	491,832			
PEPFAR shipments		482,760	-	-	-			
Global Fund shipments		591,674	40,687	506,020	-			
Treasury CPF shipments		-	207,489	-	-	14303	27290	41593
MOH shipments		-	91,600	100,000	-			
Abacavir/Lamivudine FDC (120mg/60mg) Tablets								
Consumption (actual issue at the end of each period)	64,400	701,739	560,591	471,756	669,636			
PEPFAR shipments		-	-	-	-			
Global Fund shipments		407,128	300,000	751,792	334,000			
Treasury CPF shipments		-	-	-	-	17,414	17,813	35,227
MOH shipments		-	-	-	-			
Dolutegravir (50mg) Tablets								
Consumption (actual issue at the end of each period)	25,000	534,625	491,803	407,868	439,824			
PEPFAR shipments		527,600	436,000	285,355	-			
Global Fund shipments		47,040	44,062	269,000	-			
Treasury CPF shipments	25,000	47,000	-	-	-	4,742	6,532	11,274
MOH shipments		-	-	-	-			
Atazanavir/Ritonavir (300/100mg) Tablets								
Consumption (actual issue at the end of each period)	-	778,993	809,772	942,152	937,524			
PEPFAR shipments	280,365	813,608	-	-	-			
Global Fund shipments		196,345	348,557	823,372	-			
Treasury CPF shipments		100,000	138,740	570,492	-	23,974	48,300	72,274
MOH shipments		-	260,216	-	-			
Lopinavir/Ritonavir (200/50mg) Tablets								
Consumption (actual issue at the end of each period)	18,451	179,301	105,470	60,780	60,780			
PEPFAR shipments		176,850	-	-	-			
Global Fund shipments		-	-	-	-			
Treasury CPF shipments		-	-	-	-			

MOH shipments		-	-	-	-			
Lopinavir/ritonavir (100mg/25mg) Tablets						**4,192**	**7,038**	**11,230**
Consumption (actual issue at the end of each period)	10,243	94,345	11,319	23,571	23,571			
PEPFAR shipments		-	-	-	-			
Global Fund shipments		28,737	20,000	-	-			
Treasury CPF shipments		-	-	-	-			
MOH shipments		-	6,000	-	-			
Tenofovir/Emtricitabine (300/200mg) Tablets								
Consumption (actual issue at the end of each period)	45,569	404,310	570,061	630,889	734,280			
PEPFAR shipments		-	150,000	250,000	-			
Global Fund shipments		-	609,022	768,889	-	**63,510**	**-**	**63,510**
Treasury CPF shipments		-	-	-	-			
MOH shipments		-	80,000	-	-			

Source: KEMSA tracker (ARV shipments and Patients by regimen and by gender)

Table 4: ARVs by PSM Funder and Class of Use

Class of use	ARV, Form, and Pack size	Manufacturer	PSM funder
Adult 1st Line and PMTCT	TDF/3TC/DTG 300/150/50mg FDC (90 tablets)	*Data unavailable*	GF + PEPFAR
	TDF/3TC/DTG triple FDC (30 tablets)	*Data unavailable*	Govt.
Adult/Peds 2L	TDF/3TC (300/300mg) FDC (60 tablets)	*Data unavailable*	PEPFAR
HIV Prevention	TDF/FTC (300/200mg) FDC (60 tablets)	*Data unavailable*	GF + Govt.
Peds 1st Line	ABC/3TC (120/60mg) FDC	*Data unavailable*	GF
Adult 2nd Line	AZT/3TC (300/150mg) FDC (60 tablets)	*Data unavailable*	GF
Adult 2nd Line	ATV/r (300/100mg) FDC (30 tablets)	*Data unavailable*	PEPFAR + Govt.
Adult/PMTCT	DTG (50mg) singles (30 tablets)	*Data unavailable*	PEPFAR
Peds PMTCT	AZT liquid (10mg/ml)	*Data unavailable*	Govt.
Peds PMTCT	NVP liquid (100ml)	*Data unavailable*	GF + PEPFAR

Source: KEMSA tracker (patients by regimen and by gender)

Table 5: Evolution of Department of Health and Human Services and WHO Guidelines from 1998-2013.*

Department of Health and Human Services Guidelines		Date	World Health Organization Guidelines	
"Preferred" ART Regimens	CD4 Threshold for ART Initiation		Recommended ART Regimens	CD4 Threshold for ART Initiation
IDV, NFV, RTV, SQV, or SQV/RTV + AZT/ddI, d4T/ddI, AZT/ddC, AZT/3TC, or d4T/3TC	<500	6/1998		
EFV, IDV, NFV, RTV, SQV, or SQV/RTV + AZT/ddI, d4T/ddI, AZT/ddC, AZT/3TC, or d4T/3TC	<500	12/1998		
EFV, IDV, NFV, RTV, SQV, or SQV/RTV + AZT/ddI, d4T/ddI, AZT/ddC, AZT/3TC, d4T/3TC, or ddI/3TC	<500	1999		
EFV, IDV, ~~NFV, RTV,~~ SQV, or SQV/RTV + AZT/ddI, d4T/ddI, ~~AZT/ddC,~~ AZT/3TC, d4T/3TC, or ~~ddI/3TC~~	<500	2000		
EFV, IDV, IDV/r, NFV, SQV/r, or LPV/r + AZT/ddI, d4T/ddI, AZT/3TC, or d4T/3TC	<200^	2001		

EFV, IDV, IDV/r, NFV, SQV/r, or LPV/r + ddI/3TC, AZT/ddI, d4T/ddI, AZT/3TC, or d4T/3TC	<200^	8/2001		
		2002	EFV, PI/r, NFV, or ABC + AZT/3TC	<200
EFV + 3TC + (d4T, AZT, or TDF) or LPV/r + 3TC + (d4T or AZT)	<200^	7/2003		
EFV + (3TC or FTC) + (d4T, AZT, or TDF) or LPV/r + 3TC or + (d4T or AZT)	<200^	11/2003	EFV, ~~PI/r, NFV, ABC,~~ or NVP + 3TC + (AZT or d4T)	<200
EFV + (3TC or FTC) + (~~d4T~~, AZT, or TDF) or LPV/r + (3TC or FTC) + (~~d4T~~ or AZT)	<200 (AI) <350 (BII)	2005		
EFV, ATV/r, FPV/r, or LPV/r + AZT/3TC or FTC/TDF	<200 (AI) <350 (AII)	2006		
EFV, ATV/r, FPV/r, or LPV/r + ABC/3TC, ~~AZT/3TC~~ or FTC/TDF	<200 (AI) <350 (AII)	1/2008		
EFV, ATV/r, DRV/r, FPV/r, or LPV/r + ~~ABC/3TC~~ or FTC/TDF	<200 (AI) <350 (AII)	11/2008		
EFV, ATV/r, DRV/r, ~~FPV/r, LPV/r~~, or RAL + FTC/TDF	<350 (AI) <500 (A/B-II) >500 (B/C-III)	2009	EFV or NVP + (3TC or FTC) + (AZT ~~d4T~~ or TDF)	<350
EFV, ATV/r, DRV/r, or RAL + FTC/TDF	<350 (AI) <500 (AII) >500 (BIII)	2012		
EFV, DRV/r, ATV/r, or RAL + FTC/TDF	<350 (AI) <500 (AII) >500 (BIII)	2013	~~EFV NVP~~ + (3TC or FTC) + (~~AZT~~ TDF)	<500

ART = combination antiretroviral therapy; IDV = indinavir; NFV = nelfinavir; RTV = treatment-dose ritonavir; SQV = saquinavir; EFV = efavirenz, AZT = zidovudine; ddI = didanosine; d4T = stavudine; ddC = zalcitabine; 3TC = lamivudine; r = pharmacologic-boosting dose of ritonavir; ABC = abacavir; TDF = tenofovir disoproxil fumarate; FTC = emtricitabine; PI = protease inhibitor; NVP = nevirapine; ATV = atazanavir; FPV = fosamprenavir; DRV = darunavir; RAL = raltegravir.

^Treatment should generally be offered for 350-500, though controversy existed.

*Shading represents addition to guidelines. Currently, under the test-all/treat-all strategy, treatment is offered to all eligible PLHIV regardless of their CD4 threshold and optimization is centred around mostly fixed-dose-combination medicines for better adherence and supply chain efficiencies.

Annex – 2: ARVs producers in Kenya and Review documents

ARV Producers in Kenya with acceptable GMP status.

a. Cosmos Ltd (stopped production due to WHO PQ requirements and change of regimen)
b. Universal Corporation Limited

KELIN
Reclaiming Rights, Rebuilding Lives

NAIROBI OFFICE
Kuwinda Lane, Off Lang'ata Road, Karen C
P O Box 112 - 00202, KNH Nairobi
Tel: +254 020 2515790
Mobile: +254 710 261 408 / +254 788 220 300
Fax: 020 386 1390

KISUMU OFFICE
Nyalenda Railways Estate, Block 9/220
Off Nairobi Road Opposite YMCA
P.O Box 7708 - 40100, Kisumu - Kenya
Tel: +254 057 204 1001/+254 020 251 5790
Cell: +254 716 978 740/+254 710 261 408