Market Intelligence Study of Priority HIV and TB Products in Kenya towards the Development of Strategic Interventions

JULY 2024

ITPC
INTERNATIONAL TREATMENT PREPAREDNESS COALITION

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Disclaimer

The findings and recommendations in this report do not necessarily represent the views of the organizations involved or their respective management teams.

Abbreviations

3TC	–	Lamivudine (ARV)
ABC	–	Abacavir
AZT	–	Zidovudine
ATV/r	–	Atazanavir/Ritonavir
DTG	–	Dolutegravir
DRV	–	Darunavir
EFV	–	Efavirenz
ETV	–	Etravirine
FTC	–	Emtricitabine
LPV/r	–	Lopinavir/Ritonavir
NVP	–	Nevirapine
INH	–	Isoniazid
RAL	–	Raltegravir
RPT	–	Rifapentine
TDF	–	Tenofovir
AIDS	–	Acquired Immune Deficiency Syndrome
ART	–	Anti-Retroviral Therapy (or Treatment)
ARVs	–	Anti-Retroviral (Drug or Medicine)
APIs	–	Active Pharmaceutical Ingredients
FDA	–	Food and Drug Authority (drug regulatory standard of the United States)
FY	–	Financial Year
GDF	–	Global Drug Facility (for TB medicines)
GHSC	–	Global Health Supply Chain
GF	–	The Global Fund
HIV	–	Human Immuno-deficiency Virus
ITPC	–	International Treatment Partners Coalition
KEMSA	–	Kenya Medical Supplies Authority
KeLIN	–	Kenya Ethical and Legal Issues Network
LMICs	–	Low and Middle-Income Countries
LM/LPP	–	Local Manufacturing / Local Pharmaceutical Production
MOF	–	Ministry of Finance (Treasury)
MOH	–	Ministry of Health
MPP	–	Medicines Patent Pool
NQCL	–	National Quality Control Laboratories
PEPFAR	–	President's Emergency Plan For Aids Relief
PLHIV	–	People Living With HIV
PMPA	–	Pharmaceutical Manufacturing Plan for Africa
PPB	–	Pharmacy and Poisons Board of Kenya
PPM	–	Pooled Procurement Mechanism (of the Global Fund)
PSM	–	Procurement and Supply Management
LPP	–	Local Pharmaceutical Production
LM	–	Local Manufacturers
PQ	–	Pre-qualification (regulatory standard of the World Health Organization)
PSM	–	Procurement and Supply Management
PVAC	–	Presidential Initiative for Unlocking Health Value Chains
QA	–	Quality Assurance
QC	–	Quality Control

TRIPS	–	Trade Related aspects of Intellectual Property
SRA	–	Stringent Regulatory Authorities
USAID	–	United States Agency for International Development
WHO	–	World Health Organization of the United Nations

EXECUTIVE SUMMARY

This report outlines the findings of a study carried out for KELIN, within the broader ITPC Solidarity Project titled: "Supporting the use of TRIPS flexibilities and other intellectual property related solutions to facilitate access to health products." The Market Patent Intelligence study was conducted to support the identification of priority HIV and TB health products for the development of strategic intervention and is anchored in the Solidarity Project in Kenya.

The study was conducted over a period of 30 days spread between June and July 2024. Due to time constraints amidst political turbulence because of a controversial Finance Bill 2024, a rapid desk-based review was carried out leveraging several key institutional documents e.g. The National Forecasting and Quantification 2023-2024 report, KEMSA tender data, Policy reports, and Global reference pricelists incl. GHSC-PSM, Global Fund PPM, CHAI ceiling pricelist, GDF list.

The study established some key findings: -

i. All products listed in the analysis (incl. those already off-patent) were registered with the Pharmacy Poisons Board and manufactured under license by India generic manufacturers.
ii. MOH Kenya (through KEMSA as their procurement agents) imports all its ARVs and TB medicines, and any locally procured TB drugs were through local distribution agents of foreign manufacturers
iii. Over the last 2 decades, the Medicines Patent Pool (MPP) continued to partner with Patent-holders to negotiate public health-driven licenses with these patent holders. Through this initiative, sublicenses have been extended to generic manufacturers and product developers, thus supporting access to those treatments in >123 Generic-Accessible LMICs incl. Kenya.

The Market Patent Intelligence study was conducted to support the identification of priority HIV and TB health products for the development of strategic intervention and is anchored in the Solidarity Project in Kenya.

Over the last 2 decades, the Medicines Patent Pool (MPP) continued to partner with Patent-holders to negotiate public health-driven licenses with these patent holders.

iv. MPP has so far signed agreements with 22 patent holders covering 13 ARVs, 1 TB treatment, 1 Cancer treatment, 1 HIV diagnostic platform, 4 Long-Acting Technologies, and 3 Hep C direct-acting antivirals. More work is needed to expanded access in TB, Cancer and Hep-C treatments.

v. For HIV, 97.5% or 1,243,701 out of 1,276,107 Adult patients and 87% or 43,730 out of 50,110 Peds patients were on key regimens for which Kenya had significant price advantages, volumes, and some ARVs were already off-patent.

vi. 0.15% of Adults and 0.15% of Peds on ART were on expensive 3rd Line regimens, some marked by WHO as limited use, with implications that generic manufacturers are disincentivized to produce them as they don't yield economies of scale from a business sense. However, only two of these limited-use ARVs (Peds DRV 75mg and 150mg) yielded huge price efficiencies for KEMSA compared to global reference prices. The rest were not listed in reference pricelists.

vii. Kenya (KEMSA) was found to be largely price-efficient in key ARVs despite some of the global reference prices having the advantage of lacking additional freight, duty, insurance costs which KEMSA prices already included.

viii. For TB drugs, Kenya prices were quoted at the most basic unit (per pill) in some cases, a dissimilarity from global reference prices that were quoted based on full-course treatment or per pack.

Regulatory and Policy issues

Kenya's PPB is yet to attain the WHO Regulatory Maturity Level 3 that has already been achieved by six (6) other African countries and two (2) Asian countries (India and China) where the majority of Africa's medicines are sourced based on the WHO RSS database.

Country	Regulatory Agency	Regulatory Maturity	Scope	Year Achieved
Tanzania	TMDA	Maturity Level 3	• Medicines and imported vaccines	May 2018
Ghana	FDA	Maturity Level 3	• Medicines and imported vaccines	April 2020
Nigeria	NAFDAC	Maturity Level 3	• Medicines and imported vaccines	March 2022
Egypt	EDA	Maturity Level 3	• Vaccines (producing)	March 2022
South Africa	SAHPRA	Maturity Level 3	• Vaccines (producing)	October 2022
Zimbabwe	MCAZ	Maturity Level 3	• Medicines and imported vaccines	June 2024
India	CDSCO	Maturity Level 3	• Vaccines • Licensing of premises, market surveillance and control, regulatory inspections, and national regulatory system	July 2017
		Maturity Level 4	• Clinical trial oversight, marketing authorization, vigilance, laboratories, and lot release (ML4)	
China	NMPA	Maturity Level 3	• Vaccines	July 2022

 Source: WHO RSS database

While Kenya is lagging, possibilities exist if Africa's regulatory maturity is leveraged with significant investment and international support to integrate African medicines-producing economies into the global value chain of medical products. This would be a great way to solve the intractable global challenge of how to achieve global health security in a way that enables the people of Africa to benefit at the same time as everyone else.

Unlike international Treaties like the Pandemic Agreement, this approach would be attainable and a more practical solution to negotiating treaties that require other countries to sacrifice their interests for the benefit of people in other countries. The intention of international treaties like the Pandemic Accord is good but impractical and may likely never be the feasible solution that the world and Kenya need.

As per Market Access Africa's monthly regulatory newsletter (1st-5th editions), obtaining consolidated intelligence from National Regulatory Authorities (NRAs) across Africa is one of the most frequently cited frustrations by biotech innovators. However, progress has been witnessed recently on 17th May 2024 when PPB hosted a World Bank delegation keen on strengthening the regulatory capacity and understanding the mandate of PPB and its progress towards attaining WHO maturity level 3 status and exploring potential collaborations to strengthen regulatory frameworks and address shared sector challenges in pharmaceuticals.

Subsequently, in June 2024, a USFDA delegation visited the MOH and the PPB and signed a Statement of Cooperation (SOC) with the PPB to enhance cooperative engagement in regulatory and scientific matters and public health protection. The delegation also held talks with WHO-Kenya (and discussed regulatory work in Africa to identify collaboration opportunities) as well as a roundtable with Kenyan pharmaceutical leaders to explore improving pharmaceutical manufacturing, noting Kenya's emergence as a pharmaceutical hub in East Africa. As such, global efforts are geared to prime Kenya for the next frontier in the local manufacturing agenda.

Voluntary Licensing and Local Manufacturing issues

Earlier attempts by Local manufacturers to produce ARVs through Voluntary Licensing were grossly frustrating despite ARVs being registered in Kenya. Prior voluntary licensing from European producers (GSK and Boehringer) stopped as APIs were still expensively sourced from India, but production was not sustainable due to the inconsistent application of WHO-GMP and WHO-PQ as standards on LM[1] without clear protocol guidance and threshold requirements, resulting in Local Manufacturers ceasing ARV production altogether.

Recommendations and Conclusion

For HIV, while the present conundrum to increasing access to treatment in Kenya is less supply security concern and more limited access to optimal diagnostic testing, the same cannot be said of TB and Hepatitis products despite in most cases, the latter two diseases are comorbidities in PLHIV patients.

The landscape for sustainable, resilient local production in Kenya is still not promising, despite the availability of know-how, skills, and lessons learned from recent pandemic-related supply challenges including stock-outs, and hitches in the supply of APIs that dented an already existing ART regime. The lives of PLHIV are largely dependent on the existing ARV supply value chain currently pegged on a 90% imported and donor-supported PSM mechanism. This is not sustainable in the event of global changes in the current supply paradigm. A pro-local pharmaceutical framework must be adopted similar to Nigeria's Presidential PVAC Initiative to support and sustain local pharma manufacturing, supply, and availability of quality essential ARVs and TB medicines. To promote Local Manufacturers, an Executive Order would help address these barriers and secure all other disparate ongoing efforts to catalyze local production.

This study recommends a critical review of the health policy, regulatory, and legislative frameworks for coherence and strengthening to ensure consistent implementation in health service delivery. From policy, legislative, and regulatory perspectives, address government's lack of political will that impedes local manufacturers from participating in a level playing field with foreign manufacturers and importers, as well as a critical review into the economic, value-chain, infrastructure, and human resource issues that present challenges to the sustainability of the local business model.

[1]Note: LM used interchangeably with LPP

1.0 INTRODUCTION

HIV and Tuberculosis are the global most severe and interconnected diseases, with TB as the leading cause of death among People Living with HIV. More than 2 decades of successes in HIV and TB treatment have impacted the lives of tens of millions of PLHIV, influencing national and global decisions and elevating PLHIV voices. The 20+ years of HIV treatment success have been underpinned by: -

i. New product development and introduction
ii. Optimization of guidelines and treatment options
iii. Complementary capacity-building initiatives and service-delivery improvement
iv. Health systems strengthening across national and sub-national cascades

1.1 Regional Epidemiology Outlook

However, unequal progress persists within Sub-Sahara Africa (SSA) as some key groups and geographies are still left behind and inequalities are masked by high-level reporting across Treatment and Diagnostic cascades. Below are the pending gaps in realizing treatment targets:

a) Treatment Access

- Overall, **treatment access** is at **88%** (both Peds and Adults who know their status and are on ART) across Africa, but Children are still left behind in treatment as national programs are yet to achieve parity in coverage between Peds and Adults, with **52%** Peds compared to **76% Adults** on ART regionally.
- Context-dependent, but Key Populations and Men are still less likely to access care and treatment or to enroll in ART.
- Inconvenient care is causing significant 'cycling' as the current delivery models don't meet unique patient needs (e.g. between 20% - 50% of ART initiates across Sub-Sahara Africa are re-initiations, hence the need to scale-up successful Differentiated Service Delivery or DSD models).
- Weak Data Systems with untracked *"silent transfers"* still challenge measuring last mile targets (including differences in subnational ART coverage)

b) Diagnostic Testing

- Overall, the **suppression rate** is at **92%** (both Peds and Adults on ART who have suppressed viral load) but Gender Gaps still exist as less VL suppression is seen among men compared to women in all Sub-Sahara Africa regions.
- Regional Inequalities persist as there is still lower Viral Suppression in francophone WCA (West and Central Africa) given lesser partner focus compared to East and Southern Africa.
- Poor Failure Management due to systemic challenges with treatment failure management, leading to patients staying on failing ARV regimens for longer than is necessary.
- Adherence Issues due to various factors e.g. poor mental health; persistent stigma including from Healthcare workers (HCWs); burden of daily dose; staying on suboptimal ART regimen that ought to have been phased-out or scaled-down e.g. LPV/r.

1.2 Kenya Epidemiology Outlook

a) HIV/AIDs

While Kenya has made remarkable progress to reduce New HIV infections, in 2022 there were 22,154 new HIV infections (i.e. 426 new HIV infections per week). About 60% (13,305) of all the estimated new HIV infections occurred among adults aged 15–34 years, with female accounting for 72% (9,627) and children aged 0-14 accounting for 20.19% (4,474) of all the estimated new HIV infections. Additionally, geographical disparity still exists with 9 high-burden counties accounting for 50.2% of the new HIV infections in Kenya.

- HIV prevalence of 3.7% across all ages (i.e. 5.3% females and 2.6% males).
- 1.4 million PLHIV (i.e. 1,309,915 Adults 15 years+ and 67,869 children aged 0-14 years).
- 1,325,161 of all ages are on ART and overall Viral Suppression is 93.5%
- New HIV infections 22,154 (i.e. 17,680 adults 15 years+ and 4,474 children 0-14 years).
- 41% of Adults' new infections occur among Adolescents and Young Persons 15-24 years (i.e. 145,152 PLHIV and 7,307 New infections are YPs aged 15-24 years, while 88,853 PLHIV and 3,244 New infections are Adolescents aged 10-19 years).
- AIDS-related deaths 18,474 (i.e. 16,169 adults 15 years+ and 2,304 children 0-14 years).

b) Tuberculosis (TB)

Kenya is one of the 30 high TB burden countries globally with an incidence of 319 per 100,000 population with estimated deaths of 17,000 in 2022. With a 95% target in 2023 of TB patients to be sustained on 3HP, the uptake was **68,557 newly enrolled PLHIV and 32% of household contacts** were on 3HP (predominantly adults PLHIV and HIV- population, but children were still using the long regimen of IPT (**optimal access inequity**).

- Only 60% of the presumptive cases identified in 2022 were investigated for TB with 41% receiving clinical diagnosis along the cascade, resulting in significant missed cases of TB.
- Drug Resistant TB treatment has a long duration of 18-24 months of treatment, with no TPT for DR TB contacts and a long turn-around time for Drug-Susceptible TB treatment (DST).
- TB prevention has low coverage of TPT among TB patient contacts, Children & Adolescents Living with HIV (CALHIV) using the long-duration regimen. (optimal access inequity).
- Long TAT for TB diagnosis leading to low diagnostics coverage of diagnostics, coupled with supply chain issues constraining access to optimal treatment.
- Lack of systematic screening to provide a deferential diagnosis (tools for DR-TB and DS-TB) has led to siloed programming for TB, thus the supply chain for products is not streamlined.
- Late case detection for linkage to optimal treatment or initiate eligible population on TPT.

3.0 METHODOLOGY

This assignment was conducted over 30 days between June and July at a time when there were disruptions due to political turbulence while KEMSA had closed its doors for a national stock-take exercise (Kemsa notice linked here).

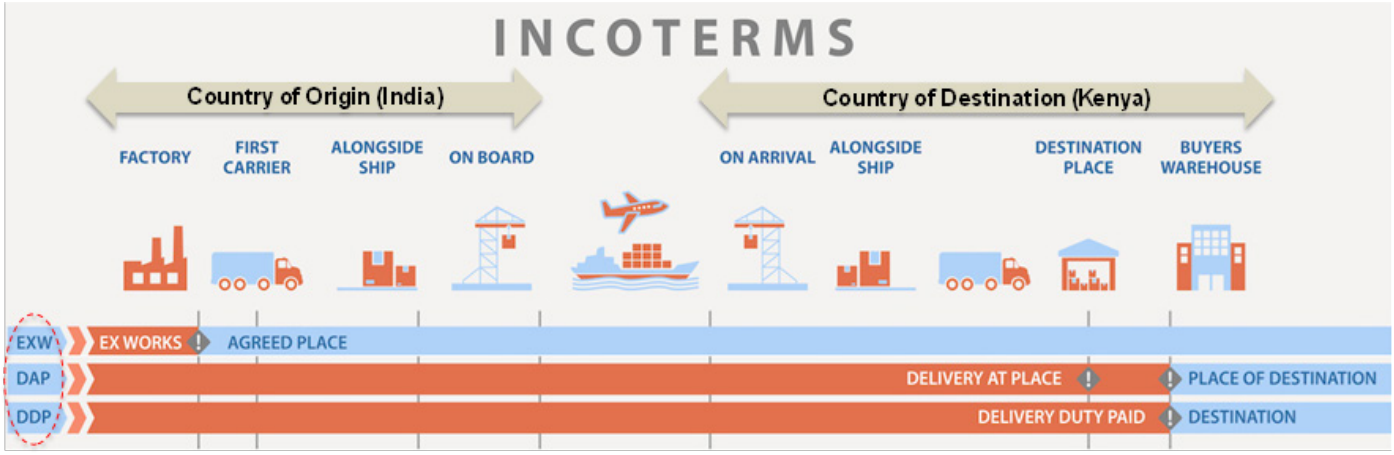
3.1 Approach

The study defined the patient pathway along the continuum of care and treatment across HIV and TB programs and developed a long list of Therapeutic and Diagnostic products used at the different stages of HIV and TB service cascades.

While HIV is the entry point, Tuberculosis (TB) is considered a co-morbidity among PLHIV and a leading cause of mortality in HIV+ patients. Among other OIs (Opportunistic Infections), HIV guidelines categorize TB as one of the Advanced HIV Diseases (AHD).

3.2 Benchmarking rationale

A price benchmarking analysis was done between KEMSA tender prices against the main global reference prices as per the applicable International Commercial Terms or INCOTERMS (*i.e. Global Fund - PPM's EXW prices, PEPFAR – PSM's DDP prices and CHAI ceiling pricelist - EXW):*

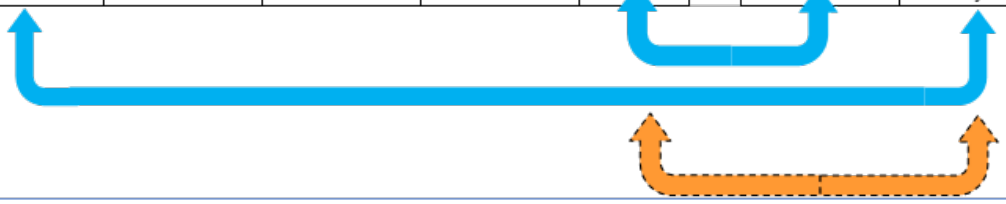


	From **Origin** to **Kenya** [KEMSA tender price build-up] =>>						Global Reference Prices	
Product Description	***EXW*** *component*	***Freight*** *component*	***Insurance*** *component*	***Duty*** *component*	**DAP (KEMSA)**		**DDP** [Pepfar PSM]	**EXW** [GF's PPM]
TDF/FTC (300/200mg)	x	x	x	x	x		y	
ABC/3TC (120/60mg)	x							y

Benchmark Key:

Optimal

Sub-optimal



- KEMSA tender prices are DAP (Delivery-At-Place) inclusive
- Global Fund PPM prices are EXW (Ex-Works) at the India Generic supplier's factory
- USAID/Pepfar PSM prices are DDP (Duty-and-Delivery-Paid) at Destination Country

3.3 Limitations in Benchmarking Approach

- Despite KEMSA's DAP prices included additional costs of insurance, duty and freight, they were still lower than GDF's EXW and Global Fund's EXW prices which did not include these extra costs. However, benchmarking was challenging where KEMSA prices were quoted at the most basic unit (per pill or tablet) while global reference prices were quoted based on the full-treatment course (e.g. 12-weeks for TB medicines):
- In terms of comparing apples-to-apples, benchmarking KEMSA's DAP prices against USAID Pepfar's DDP prices was the most optimal as they both included the additional costs.
- In terms of dissimilar comparison (apples-to-oranges), benchmarking KEMSA DAP prices against GF's EXW prices was sub-optimal as EXW prices do not include additional costs of freight, insurance, duty, and delivery up to the destination (Kenya).
- Access to sensitive and confidential supplier bidding documents was unsuccessful within the timeframe of this study as express permission from the KEMSA board was needed since price/cost-breakdown information is competitive between suppliers, which could lead to litigation. As such, only aggregated prices were used in the analysis.
- Due to a lack of response from KEMSA, it was not possible to obtain any tender information on supply contracts executed and related supplier names and volumes allocated to each.
- TB medicines presented the most challenges with gaps in Kenya's GF-NFM application where the product specifications were not well articulated and prices were off-the-chart based on units of measure, while some global reference prices quoted full treatment course of the regimen instead of per pack, which was challenging for a product-based comparison as it was not possible to unbundle such cost build-up. Assumptions have been made to derive the per-pack pricing as well as make the best-fit conclusion regarding the product specification.

4.0 KEY FINDINGS

All ARVs and TB medicines procured by KEMSA are registered with the Pharmacy and Poisons Board (PPB) of Kenya, with some like Lamivudine (3TC) already off-patent and under generic licensing for the longest time in the history of HIV-Aids treatment.

Over 2 decades, The Medicines Patent Pool has continued to sign licenses with Patent-holders for generic production of these drugs, benefitting approx. 193 LMICs across the world (of which Kenya is a part). Together, these 193 Generic-Accessible countries (GA-LMICs) is home to 90.5% of PLHIV (https://medicinespatentpool.org/license-post/)

Most of the generic partners and product developers are in India (which a couple others in China as API producers). Kenya is yet to harness the opportunity provided by these licenses due to a number of factors including political-will, policy and regulatory restrictions, value-chain and industry development, human resources etc.

HIV and TB drugs are mainly funded by USAID/PEPFAR and Global Fund, with the Government accounting for a very small portion of the procurement budget. To qualify for these tenders, the products and manufacturers must be SRA approved by either US-FDA or WHO-PQ, for only one Kenya manufacturer has a WHO-PQ but is not incentivised to product generic ARVs.

KEMSA procurement tenders for ARVs and TB medicines are >90% funded by PEPFAR and Global Fund, with a paltry 10% funded by Government CPF (counterpart funding). This is unsustainable in the advocacy for local production as PEPFAR only procure FDA-approved products while The Global Fund only procure ERP-approved or WHO Prequalified products, a status for which only one of 39 Kenya pharma manufacturers qualify for but is disincentivised to pursue.

4.1 Price-benchmark results

- For treatment ARVs, based on dissimilar incoterm (DAP vs. EXW) and similar incoterm (DAP vs. DDP), KEMSA was price efficient in both cases for key ARVs which comprising the greatest number of ART patients (i.e. >97% Adult and >87% Peds)
- For the two HIV-Prevention ARVs, KEMSA was price efficient at US$ 0.70 per pack for TDF/FTC but price inefficient at US$ 0.14 per pack for TDF/3TC compared GF's EXW price (though KEMSA prices include additional costs of freight, insurance, and duty). As such, the margin.

- The most difficult-to-source medicines have the highest prices but very few patients on them. For HIV, these were mainly 3rd Line regimens (i.e. Darunavir 600mg, Ritonavir 100mg, Raltegravir 400mg, and Etravirine 100mg which had only 0.15% of all adult patients or 1,959 patients using these ARVs; With Darunavir 75mg and 150mg, and Ritonavir 100mg for Peds accounting for 77 patients or 0.15% of all Peds patients on ART).
- Sourcing TB medicines was characterized by extremely long lead times, which often resulted in stockouts. The two main windows for TB procurement were either The Global Drug Facility (GDF) or the more expensive individual tenders with private suppliers. The lack of credible TB-patient demographics did not help with proper quantification, creating uncertainty in proper supply planning and stock security challenges.
- HIV products generally do not have any licensing or supply security concerns except for a few 3rd line treatment regimens and low-volume Prevention and Treatment products.

4.2 Adult ARVs

Guidelines Class (ART)	Key Regimen	Patients	%age	Category	Product	Registered in LMICs	(GF-PPM Oct 2023)	E-catalog (PSM Jan. 2024)	KEMSA DAP 2023	Supply Plan 23/24	6M Supply Plan 23/24	FY23/24 Quantity	FY24/25 Quantity	FY25/26 Quantity	Manufacturer
Adult 1L (a)	TDF/3TC/DTG (TLD)	1,173,110	91.93%	Adults Tx	TLD (300/300/50mg) - 30 tabs	Yes	$ 3.60	$ 5.49	$ 3.04	444,944	684,944	496,629	502,897	503,612	Over 10 generics suppliers with WHO PQ or tentative US FDA approval
				Adults Tx	TLD (300/300/50mg) - 90 tabs	Yes	$ 10.20	$ 10.60	$ 9.09	3,667,469	6,067,469	4,720,092	4,801,801	4,794,506	Over 10 generics suppliers with WHO PQ or tentative US FDA approval
				Adult Px - PrEP	TDF/3TC (300/300mg) - 30 tabs	3TC off-patent	$ 3.20	$ 3.09	$ 3.34	16,849	240,000	485,706	450,198	455,445	Aurobindo, Cipla, Hetero, Lupin, Macleods, Viatris, Sun Pharma, Celltrion.
				Adults Tx	DTG 50mg - 30 tabs	Yes	$ 1.90	$ 2.20	$ 1.26	489,417	394,355	407,877	439,827	450,474	Over 11 generics suppliers with WHO PQ or tentative US FDA approval
Adult 1L (d)	ABC/3TC/DTG (ALD)	7,899	0.62%	Adults Tx	ABC/3TC (600/300 mg) - 30 tabs	Yes	$ 7.85	$ 12.35	$ 6.30	-	100,000	297,029	306,833	314,023	
				Adults Tx	DTG 50mg - 30 tabs	Yes	$ 1.90	$ 2.20	$ 1.26	489,417	394,355	407,877	439,827	450,474	Over 11 generics suppliers with WHO PQ or tentative US FDA approval
Adult 1L (e)	TDF/3TC + ATV/r	1,915	0.15%	Adult Px - PrEP	TDF/3TC (300/300mg) - 30 tabs	3TC off-patent	$ 3.20	$ 3.09	$ 3.34	16,849	240,000	485,706	450,198	455,445	Aurobindo, Cipla, Hetero, Lupin, Macleods, Viatris, Sun Pharma, Celltrion.
				Adults Tx	ATV/r (300/100 mg) - 30 tabs	Yes	$ 10.95	$ 10.95	$ 9.97	688,492	1,138,492	942,152	937,519	948,427	6 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 1L (b)	TDF/3TC/EFV (TLE)	1,324	0.10%	Adults Tx	TLE (300/300/400mg) - 30 tabs	Yes	$ 4.95		$ 5.50	-	-	40,809	41,328	41,745	
Adult 1L (c)	AZT/3TC/DTG (ZLD)	1,317	0.10%	Adults Tx	AZT/3TC (300/150 mg) - 60 tabs	Yes		$ 6.25	$ 5.05	-	100,000	519,523	491,826	498,144	
				Adults Tx	DTG 50mg - 30 tabs	Yes	$ 1.90	$ 2.20	$ 1.26	489,417	394,355	407,877	439,827	450,474	Over 11 generics suppliers with WHO PQ or tentative US FDA approval
Adult 1L (h)	AZT/3TC + ATV/r	452	0.04%	Adults Tx	AZT/3TC (300/150 mg) - 60 tabs	Yes		$ 6.25	$ 5.05	-	100,000	519,523	491,826	498,144	
				Adults Tx	ATV/r (300/100 mg) - 30 tabs	Yes	$ 10.95	$ 10.95	$ 9.97	688,492	1,138,492	942,152	937,519	948,427	6 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 1L (f)	TDF/3TC + LPV/r	361	0.03%	Adult Px - PrEP	TDF/3TC (300/300mg) - 30 tabs	3TC off-patent	$ 3.20	$ 3.09	$ 3.34	16,849	240,000	485,706	450,198	455,445	Aurobindo, Cipla, Hetero, Lupin, Macleods, Viatris, Sun Pharma, Celltrion.
				Adults Tx	LPV/r (250 mg) - 120 tabs	Yes	$ 17.95		$ 18.65	-	-	60,790	2,136	2,136	7 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 1L (g)	AZT/3TC + LPV/r	98	0.01%	Adults Tx	AZT/3TC (300/150 mg) - 60 tabs	Yes		$ 6.25	$ 5.05	-	100,000	519,523	491,826	498,144	
				Adults Tx	LPV/r (250 mg) - 120 tabs	Yes	$ 17.95		$ 18.65	-	-	60,790	2,136	2,136	7 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 2L (a)	ATV/r - based regimen	70,591	5.53%	Adults Tx	ATV/r (300/100 mg) - 30 tabs	Yes	$ 10.95	$ 10.95	$ 9.97	688,492	1,138,492	942,152	937,519	948,427	6 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 2L (b)	LPV/r - based regimen	9,412	0.74%	Adults Tx	LPV/r (250 mg) - 120 tabs	Yes	$ 17.95		$ 18.65	-	-	60,790	2,136	2,136	7 generics suppliers with WHO PQ and/or US FDA tentative approval
Adult 2L (c)	DTG - based regimen	7,669	0.60%	Adults Tx	DTG 50mg - 30 tabs	Yes	$ 1.90	$ 2.20	$ 1.26	489,417	394,355	407,877	439,827	450,474	Over 11 generics suppliers with WHO PQ or tentative US FDA approval
Adult 3L (a)	3L regimen	566	0.04%	Adults Tx	DRV (600 mg) - 60 tabs	Yes			$ 43.20	18,943	3,304	6,400	6,480	6,582	
				Adults Tx	RTV (100mg) - 30 tabs	Yes			$ 8.45			3,158	3,198	3,249	
Adult 3L (b)	Other Unclassified 3L	1,393	0.11%	Adults Tx	RAL (400mg) - 60 tabs	Yes			$ 60.59			84	84	84	
				Adults Tx	ETV (100mg) - 120 tabs	Yes			$ 43.39	-	-	84	84	84	
	Total Adults on ART	1,276,107													

4.3 Pediatric ARVs

Guidelines Class (ART)	Key Regimen	Patients	%age	Category	Product	Registered in LMICs	(GF - PPM Oct. 2023)	E-catalog (PSM Jan. 2024)	KEMSA DAP 2023	Supply Plan 23/24	6M Supply Plan 23/24	FY23/24 Quantity	FY24/25 Quantity	FY25/26 Quantity	Manufacturer
Peds 1L (a)	ABC/3TC/DTG (ALD)	28,663	57.00%	Peds Tx- *Optimal*	ABC/3TC/DTG (60/30/5mg) - 90 tabs	Yes	$ 7.50								Aurobindo (US FDA), Cipla (WHO PQ), Viatris (US FDA)
				Peds Tx- *Optimal*	ABC/3TC (120/60mg) - 30 tabs D.S.	Yes	$ 2.70	$ 2.70	$ 2.50	237,536	571,536	644,445	669,636	687,947	
				Peds Tx- *Optimal*	pDTG 10mg - 90 tabs disp-scored	Yes	$ 4.30	$ 4.22	$ 4.50	63,958	128,958	110,596	119,434	122,669	Macleods (US FDA, WHO PQ), Viatris (US FDA)
Peds 1L (b)	TDF/3TC/DTG (TLD)	15,067	30.00%	Adult Px- PrEP	TDF/3TC (300/300mg) - 30 tabs	3TC off-patent	$ 3.20	$ 3.09	$ 3.34	16,849	240,000	485,706	450,198	455,445	Aurobindo, Cipla, Hetero, Lupin, Macleods, Viatris, Sun Pharma, Celltrion.
				Adults Tx	DTG 50mg - 30 tabs	Yes	$ 1.90	$ 2.20	$ 1.26	489,417	394,355	407,877	439,827	450,474	Over 11 generic suppliers with WHO PQ or tentative US FDA approval
				Adults Tx	TLD (300/300/50mg) - 30 tabs	Yes	$ 3.60	$ 5.49	$ 3.04	444,944	684,944	496,629	502,897	503,612	Over 10 generic suppliers with WHO PQ or tentative US FDA approval
				Adults Tx	TLD (300/300/50mg) - 90 tabs	Yes	$ 10.20	$ 10.60	$ 9.09	3,667,469	6,067,469	4,720,092	4,801,801	4,794,506	Over 10 generic suppliers with WHO PQ or tentative US FDA approval
Peds 1L (c)	ABC/3TC + LPV/r	189	0.00%	Peds Tx- *Optimal*	ABC/3TC (120/60mg) - 30 tabs D.S.	Yes	$ 2.70	$ 2.70	$ 2.50	237,536	571,536	644,445	669,636	687,947	
				Peds Tx- *Optimal*	LPV/r (125 mg) - 60 tabs heat stable	Yes	$ 5.50	$ 6.50	$ 5.50	-		23,554			Tablet: 6 generic suppliers with US FDA tentative approval and/or WHO PQ
Peds 1L (d)	ABC/3TC + EFV	161	0.00%	Peds Tx- *Optimal*	ABC/3TC (120/60mg) - 30 tabs D.S.	Yes	$ 2.70	$ 2.70	$ 2.50	237,536	571,536	644,445	669,636	687,947	
				Peds Tx- *Limited*	EFV (200mg)	Yes									
Peds 1L (e)	ABC/3TC + NVP	39	0.00%	Peds Tx- *Optimal*	ABC/3TC (120/60mg) - 30 tabs D.S.	Yes	$ 2.70	$ 2.70	$ 2.50	237,536	571,536	644,445	669,636	687,947	
				Peds Tx- *Optimal*	NVP (10 mg/ml) Oral soln 100ml	Yes		$ 1.75	$ 1.35	568,750	848,750	964,646	706,196	769,603	
Peds 1L (f)	ABC/3TC + RAL	172	0.00%	Peds Tx- *Optimal*	ABC/3TC (120/60mg) - 30 tabs D.S.	Yes	$ 2.70	$ 2.70	$ 2.50	237,536	571,536	644,445	669,636	687,947	
				Peds Tx- *Limited*	RAL (100mg) granules	Yes	$ 57.00								Merck (MSD)
Peds 1L (g)	AZT-based regimen	197	0.00%	Peds Tx- *Optimal*	AZT/3TC (60/30mg) - 60 tabs D.S.	Yes	$ 1.70	$ 1.90	$ 1.91	23,190	32,598	28,793	18,820	19,692	
				Peds Tx- *Optimal*	AZT liquid (10mg/ML) - 240ml	Yes	$ 2.15	$ 4.25	$ 2.36	201,288	201,288	167,525	111,683	111,683	
Peds 1L (h)	Other 1L regimen	736	1.00%	Peds Tx- *Limited*											
Peds 2L (a)	All 2L regimen	4,809	10.00%	Peds Tx- *Optimal*											
Peds 3L (a)	All 3L regimen	77	0.00%	Peds Tx- *Limited*	DRV 75mg - 480 tabs	Yes	$ 65.00	$ 54.00	$ 54.00	-	-	45	45	45	
				Peds Tx- *Limited*	DRV 150mg - 240 tabs	Yes	$ 65.00	$ 54.54	$ 63.11	92	92	265	265	265	
				Peds Tx- *Limited*	RTV (100mg) - 60 tabs heat stable	Yes		$ 7.00	$ 8.45	4,636	14,872	1,267	1,297	1,324	
	Total Peds on ART	50,110													

4.4 TB Medicines (Adults and Pediatrics)

Product Description	Licensing Status	GDF EXW (1Q2021)	KEMSA DAP Price	GF NFM Supply Plan 20/21	FY23/24 Quantity	FY24/25 Quantity	FY25/26 Quantity	Manufacturer
RPT/INH (300/300 mg) - FC Tabs Blisters 36	PPB registered	$ 15.00	$ 16.92		159,114	121,628	118,742	Macleods (WHO PQ), and Lupin (GF ERP, WHO-PQ expected in 2024)
Isoniazid 300mg Uncoated tabs [Blisters 672]	PPB registered	$ 13.52	$ 6.72		46,394	36,650	26,251	
Isoniazid 100mg Disp. Tabs [Blisters 100]	PPB registered	$ 10.00	$ 1.00		15,625	19,133	10,830	
Pyridoxine - 100mg HDPE jars 250	PPB registered	$ 11.55	$ 2.50		53,159	48,712	38,327	
Pyridoxine 50mg Film Coated Blisters 50	PPB registered	$ 0.70	$ 0.50		1,617	1,980	1,121	
Kanamycin cat215348(BD),Pack of 6 Vials	PPB registered		$ 90.00	4				Becton Dickinson International (BD)
Moxifloxacin cat 21539(BD),Pack of 6 Vials	PPB registered		$ 90.00	5				Becton Dickinson International (BD)
Amikacin cat 2153509BD),Pack of 6 Vials	PPB registered	$ 58.75	$ 90.00	4				Becton Dickinson International (BD)
Capreomycin cat 215351(BD),Pack of 6 Vials	PPB registered		$ 90.00	4				Becton Dickinson International (BD)
Ofloxacin cat 215352(BD),Pack of 6 Vials	PPB registered		$ 90.00	4				Becton Dickinson International (BD)
Ethionamide, 98%	PPB registered	$ 9.43		1				Kobian Kenya Limited
Prothionamid 99% + (HPLC)	PPB registered	$ 8.74	$ 240.00	1				Kobian Kenya Limited
4- Aminosalicylic Acid 99%	PPB registered		$ 240.00	1				Kobian Kenya Limited
Clofazimine	PPB registered	$ 80.80	$ 80.00	2				Kobian Kenya Limited
D-Cycloserine, 98%-	PPB registered	$ 25.90	$ 150.00	1				Kobian Kenya Limited
Linezolid, 98 + % (HPLC)	PPB registered	$ 38.91	$ 350.00	2				Kobian Kenya Limited
Moxifloxacin ;1 Gram	PPB registered	$ 16.00	$ 368.69	2				Kobian Kenya Limited
Protionamid;22 Grams	PPB registered	$ 8.74	$ 128.27	2				Kobian Kenya Limited
Ethionamide; 5 Grams	PPB registered	$ 9.43	$ 112.97	2				Kobian Kenya Limited
Amikacin;5 Grams	PPB registered		$ 689.73	2				Kobian Kenya Limited
Para Amino Salicylic Acid;5 Grams	PPB registered	$ 58.75	$ 22.00	10				Kobian Kenya Limited
Capreomycin;1 Gram	PPB registered		$ 300.12	2				Kobian Kenya Limited
Kanamycin,5 Grams	PPB registered		$ 67.22	2				Kobian Kenya Limited
Ofloxacin;10Grams	PPB registered		$ 315.39	2				Kobian Kenya Limited
Levofloxacin;1 Gram	PPB registered	$ 2.76	$ 48.23	10				Kobian Kenya Limited
D-Cycloserine;250mg	PPB registered	$ 25.90	$ 806.63	2				Kobian Kenya Limited

4.5 Medicines (Adults and Pediatrics)

The Medicines Patent Pool (MPP) continues to negotiate public health-driven licenses with patent holders and secured sublicense to generic manufacturers and product developers. Of the 22 MPP agreements and sub-licenses, 14 benefited LMICs and were found to support access to those treatments in 123 – 190 LMICs. However, all of these benefited generic ARVs but not TB or Hepatitis, and as such more work is needed to negotiate sublicenses for products to treat these two comorbidities and reduce access inequity.

		TB	Effective Coverage	BILL & MELINDA GATES MEDICAL RESEARCH INSTITUTE	TB ALLIANCE
MP Holder	Pfizer	SUTEZOLID	100%	X	
Research Institution	JOHNS HOPKINS UNIVERSITY	SUTEZOLID	100%		X

Medicine Patent Holders	Hep C	Effective Coverage	Arene Lifesciences Limited	DEXMOCO PHARMA	Cipla	HETERO	LAURUS Labs	Mylan	Remington	USV	Zydus Cadila
abbvie	GLECAPREVIR/ PIBRENTASVIR (G/P)	47.50%	X					X	X	X	
Bristol-Myers Squibb	DACLATASVIR (DAC)	65.40%		X	X	X	X	X			X

Medicine Patent Holders	HIV	Effective Coverage	adcock Ingram	BC	Arene Lifesciences Limited	AUROBINDO	Cipla	DESANO	Emcure	HETERO	LANGHUA	LAURUS Labs	LUPIN	MACLEODS	MICRO LABS LIMITED	MANGALAM	Mylan	Strides	SUN PHARMA
Bristol-Myers Squibb	ATV	89%				X	X	X	X								X		
GILEAD	FTC	90.50%	X	X	X	X		X	X			X	X	X	X				
	TAF	90.50%	X			X		X	X		X	X	X	X	X				
	TDF	90.50%	X	X	X														
MSD	RAL (Peds)	98%																	
ViiV Healthcare	ABC (Peds)	99.30%				X													
	CAB-LA (PrEP)	—				X	X										X		
	DTG (Adults)	94%	X				X	X	X	X		X	X	X	X	X	X	X	X
	pDTG (Peds)	99%	X				X	X	X	X		X	X	X	X		X	X	X
abbvie	LPV/r (Adults)	100%	X		X	X		X	X	X			X						X
	LPV/r (Peds)	100%					X			X									

5.0 RECOMMENDATIONS

To significantly and more broadly reduce new infections and improve health equity through reliable and consistent access to quality treatment, effort, and resources should be focused on: -

a) Diagnostic **testing services to identify** the remaining unidentified PLHIV and TB cases.

- While ending (especially Pediatric) AIDS is not a new call, there are now tools to achieve this e.g. Precision Public Health Approach (incl. Geo-mapping, Multi-modality testing for infants, and Better data).

b) Efforts geared towards putting **clients at ongoing risk on HIV prevention** services.

There is a critical need to scale game-changing strategies e.g.

- Catalyzing surge testing services
- Retaining clients and patients on optimal regimen
- Preventing the biggest opportunistic killers e.g. TB and Crypto
- Closing the tap on new infections through use of PrEP, PEP etc.

c) Ensure **patients on treatment achieve viral suppression.**

Overall, the prevailing HIV-access challenge in Kenya is less supply security issues and more limited access to optimal diagnostic testing services. However, this is not the same case for TB and Hepatitis where efforts should be focused on negotiating more sub-license agreements to introduce and scale up generic manufacturing and lowering access prices for both medicines and diagnostics.

The landscape for sustainable, resilient local production in Kenya is still not promising, despite the availability of know-how, skills, and lessons learned from recent pandemic-related supply challenges including stock-outs, and hitches in the supply of APIs that dented an already existing ART regime. The lives of PLHIV are largely dependent on the existing ARV supply value chain currently pegged on a 90% imported and donor-supported PSM mechanism. This is not sustainable in the event of global changes in the current supply paradigm.

The govt. must show political will by securing adequate domestic PSM financing and establishing an enabling environment for pro-local pharmaceutical framework like Nigeria's Presidential PVAC Initiative. This study recommends a critical review of the health policy, regulatory, and legislative frameworks for coherence and strengthening to ensure consistent implementation in health service delivery.

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INTERNATIONAL TREATMENT PREPAREDNESS COALITION

make medicines affordable
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