Market Intelligence Study to Support the Identification of Priority Health Products for Intervention Under the Solidarity Project in Uganda

SEPTEMBER 2024

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Acknowledgement

This study was by the Kenya Legal and Ethical Issues Ethical Issues Network on HIV and AIDS (KELIN), in collaboration with the Center for Health, Human Rights and Development (CEHURD) (Uganda), and with support from the International Treatment Preparedness Coalition Global (ITPC) (Global). The study was undertaken by Enock Kandaruku (Consultant), in coordination with the KELIN and CEHURD team comprising of Anne Lumbasi, Okania Pesa, Duke Otieno and Timothy Wafula. Technical review was provided by the ITPC Global team: Othoman Mellouk, Sergiy Kondratyuk, Morgane Ahmar and Detrich Peeler.

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List of Abbreviations

ACP	AIDS Control Program
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
CDC	Center for Disease Control and Prevention
COP	Country Operational Plan
DHIS2	District Health Information Software 2
FDC	Fixed Dose Combination
GDF	Global Drug Facility
GOU	Government of Uganda
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
ICO/IARC for	The Catalan Institute of Oncology/The International Agency Research on Cancer
JMS	Joint Medical Stores
M & E	Monitoring and Evaluation
MAUL	Medical Access Uganda Limited
MoH	Ministry of Health
MOH-DPNM	The Ministry of Health (MOH), Department of Pharmaceuticals and Natural Medicines (DPNM)
MSM	Men Who Have Sex with Men
mSTR	modified short-term treatment regimens
NMS	National Medical Stores
PEPFAR	The U.S. President's Emergency Plan for AIDS Relief.
PNFP	Private-Not-For-Profit
PPM	Pooled Procurement Mechanism
PPPY	Postdiagnosis per patient per year
PSA	Procurement Service Agent
PWID	Persons Who Inject Drugs
TB	Tuberculosis
TGF	The Global Fund
ToR	Terms of Reference
TPT	TB Preventive Therapy
VAT	Value Added Tax
UNAIDS	The Joint United Nations Programme on HIV/AIDS

1.0 BACKGROUND OF THE STUDY

1.1 Introduction

The Uganda Market Intelligence Study was commissioned by the Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN), in collaboration with the Center for Health, Human Rights and Development (CEHURD), and with support from the International Treatment Preparedness Coalition Global (ITPC). The study was undertaken as part of the Solidarity Project which aims to prevent, remove, or overcome IP-related barriers that hamper access to health products, to increase equitable access to affordable and appropriately formulated medicines, biologics, vaccines, and diagnostics for people in low and middle income countries (LMICs). This study report focuses on identifying priority health products for intervention, specifically targeting HIV and TB, with inclusion of HCV and cervical cancer.

This study was undertaken against the backdrop that while patents and other intellectual property (IP) rights can incentivize innovation, they can

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also contribute to global health inequity, especially in low and middle income countries (LMICs), which often lack access to affordable health products, including for global health emergencies and path-breaking new health products (such as long-acting [LA] technologies) for HIV, TB, and HCV (hepatitis C virus). The impact of global health inequity has been especially harsh for key and vulnerable populations (KVPs).

Through this study, critical data was collected that included epidemiology, implementation costs, and supply chain concerns, and potential impact of health products; their registration status, procurement, and demand; community needs as well as price tracking with a primary focus on HIV and TB and good extent HCV. The data was used in; 1) The identification of priority ARVs, HCV and TB medicines for intervention. 2) The development of strategic interventions for each drug identified.

1.2 Country context

Geography and Demographics: Uganda, a landlocked country in East Africa, shares borders with South Sudan, Kenya, Tanzania, Rwanda, and the Democratic Republic of Congo. Its capital city is Kampala. As of the latest data, Uganda's population stands at approximately 45.9 million (2024)[1], with an annual growth rate of 3%. Uganda ranked 166th out of 191 countries on the UNDP Human Development Index, with a religious composition in 2014 of 45.1% Protestant (including 32.0% Anglican, 11.1% Pentecostal/Born Again/Evangelical, 1.7% Seventh Day Adventist, and 0.3% Baptist), 39.3% Roman Catholic, 13.7% Muslim, 1.6% other religions, and 0.2% identifying with no religion.

Economy: Uganda's GDP reached $45.57 billion (2022)[2], with a GDP per capita of $964.4 USD. GDP real growth of 4.6% (2022), the economy heavily relies on agriculture, employing over two-thirds of the workforce. Key exports include coffee, fish, tobacco, and gold.

Challenges: Corruption; 141st of 180 countries on CPI (2023), UNDP Gender inequality; 131st of 170 countries (2021)

Health and Challenges: Uganda has Physicians' density of 0.2 doctors, nurses and midwives/1,000 population (2020)[3], Hospital beds density of 0.5 beds/1,000 population, and a high fertility rate of 5.26 children per woman. Infant mortality remains a concern, with forty-three deaths per one thousand live births. 2.31% of GDP spent on health (2022/23)[4].

[1]2024 Uganda Bureau of Statistics Census

[2]https://data.worldbank.org/

[3]Khttps://www.destatis.de/EN/Themes/Countries-Regions/International-Statistics/Data-Topic/Tables/BasicData_Physicians.html

[4]UNICEF-Uganda-Health-Budget-Brief-2022-2023

2.0 DISEASE CONTEXT

2.1 Epidemiology data: HIV

HIV Prevalence in Uganda among adults was at 5.1% (2022) with the prevalence higher in Women at 6.6% while men at 3.6%. This is lower than the region at 6.2%[5]. HIV prevalence is higher among key population at 31% among sex workers, 17% among PWID and 13% for MSM[6]. HIV new infections have been on decline from 88,000 in 2010 to 52,000 in 2022 which remains very high with the decline being 39% in 11 years. In 2023, Ugandan parliament passed Anti-Homosexuality Act which UNAIDS has warned that its passing into law would undermine Uganda's efforts to end AIDS by 2030, by violating fundamental human rights including the right to health and the very right to life. Strong performance on the 95:95:95 Cascade has been noted: As of 2022, Uganda had an estimated 1.4 million people living with HIV 90% of whom knew their status, 94% of the PLHIV who knew their status were on treatment while 94% of the PLHIV on treatment were virally suppressed.

2.1.1 Breakdown of Patient Numbers by Treatment Class and Regimen

As of the most recent data, there are approximately 1.4 million people living with HIV in Uganda. The treatment coverage is 94%, with nearly 1.21 million people on antiretroviral therapy (As of December end 2022).

Table 1: HIV Testing and Treatment Cascade

Population Group Description	Number of PLHIV (Dec 2022)	Progress on the 95-95-95 targets
Estimated Number of PLHIV	1,400,000	-
PLHIV who know their status	1,289,028	90%
PLHIV who are on ART	1,210,906	94%
PLHIV who have suppressed viral loads	1,134,636	94%

Source: UNAIDS Factsheet 2023 (Numbers as at End Dec 2022)

[5]https://www.unaids.org accessed on July 10, 2024

[6]Programmatic data

The number of PLHIV on treatment as of December 2023 and numbers projected for 2024 from Spectrum by ACP are summarized in Table 2 below.

Table 2: The number of PLHIV on treatment as of December 2023 and 2024 projections by ACP

Patient Group	Dec-23	Projection Dec-24	% Increas
0-14 years	57,385	57,231	-0.3%
15years +	1,189,194	1,245,490	4.7%
Total	1,246,579	1,302,721	4.5%

Over 90% of PLHIV on ART are First Line Patients. Over 90% of both First and 86% of Second Line PLHIV on ART have been transitioned to DTG based regimens. Of the pediatric PLHIV, 92% are first liners and 7.6% are second liners. For PLHIV >15yrs; 97% are first liners.

The Tables 3 to 7 below detail the number of patients, their distribution across the three lines of treatment and respective optimized regimens, Sector split between public and PNFP.

Table 3: Sector split for Adult and Children on ART on First- and Second-line treatment based on ACP Program Data

National pt numbers - <15yrs	PLHIV #s	Proportion
57,192		100.0%
Public sector	43,819	76.6%
PNFP Sector	13,372	23.4%

National pt numbers- >15yrs	PLHIV #s	Proportion
1,187,729		100.0%
Public	851,199	71.7%
PNFP Sector	336,531	28.3%

Table 4: ART PLHIV Numbers by Line of Treatment – December 2023

National pt numbers-< 15yrs	PLHIV #s	Proportion
57,385		100.0%
First Line	52,805	92.0%
Second line	4,387	7.6%
Third Line	193	0.3%

National pt numbers->15yrs	PLHIV #s	Proportion
1,189,194		100.0%
First Line	1,149,305	96.6%
Second line	38,424	3.2%
Third Line	1,465	0.1%

Table 5: First Line ART PLHIV Numbers by Regimen – December 2023

Adult FL Regimens- Public sector	# of PLHIV	Dec'23
TDF-3TC-DTG	807,601	97.8%
ABC-3TC-DTG	12,353	1.5%
TDF-3TC-EFV	4,266	0.5%
ABC-3TC-EFV	1,232	0.1%
TAF-FTC-DTG	-	0.0%
TDF-3TC-ATV/r	212	0.0%
AZT-3TC-EFV	81	0.0%
Total	825,746	100.0%

Adult FL Regimens -PNFP Sector	# of PLHIV	Dec'23
TDF-3TC-DTG	310,597	96.0%
ABC-3TC-DTG	7,928	2.5%
TDF-3TC-EFV	4,311	1.3%
TDF/3TC+ATV/r	430	0.1%
ABC-3TC-EFV	246	0.1%
TAF/FTC/DTG	-	0.0%
AZT-3TC-EFV	47	0.0%
Total	323,559	100.0%

Table 4: ART PLHIV Numbers by Line of Treatment – December 2023

Adult SL Regimens Public Sector	# of PLHIV	Dec'23
TDF/3TC+DTG	12,691	49.9%
AZT/3TC+DTG	7,003	27.5%
ABC/3TC+DTG	2,319	9.1%
AZT/3TC+ATV/r	1,237	4.9%
TDF/3TC+ATV/r	1,179	4.6%
ABC/3TC+ATV/r	644	2.5%
AZT/3TC+LPV/r	382	1.5%
ABC/3TC+LPV/r	-	0.0%
TDF/3TC+LPV/r	-	0.0%
Total	25,453	100.0%

Adult SL Existing Regimens PNFP Sector	# of Clients	Dec'23
TDF/3TC+DTG	7,304	56.3%
AZT/3TC+DTG	2,439	18.8%
ABC/3TC+DTG	1,323	10.2%
TDF/3TC+ATV/r	737	5.7%
AZT/3TC+ATV/r	461	3.6%
ABC/3TC+ATV/r	300	2.3%
AZT/3TC+LPV/r	174	1.3%
TDF/3TC+LPV/r	156	1.2%
ABC/3TC+LPV/r	77	0.6%
Total	12,971	100.0%

Table 7: Regimen Breakdown for PLHIV on Third Line ART

Adults and Children Aged 10 years +	
Regimen	**% age**
TDF+3TC+DTG+DRV+RTV	58.7%
DRV+RTV+DTG	13.9%
DRV+RTV+DTG+ETV	7.1%
DRV+RTV+RAL	4.8%
DRV+RTV+ETV+RAL	3.7%
TDF+3TC+DTG+ATV/r	2.8%
DRV+RTV+ETV	2.2%
TDF+3TC+DTG	2.0%
TDF+3TC+DRV+RTV	1.7%
AZT+3TC+DTG	1.5%
ABC+3TC+RAL	0.4%
ABC+3TC+DTG+DRV+RTV	0.4%
TDF+3TC+RAL	0.3%
ABC+3TC+DRV+RTV	0.2%
ABC+3TC+RAL+DRV+RTV	0.2%
TDF+3TC+DTG+DRV+RTV+ETV	0.1%
AZT+3TC+DRV+RTV	0.1%
Total	**100.00%**

Children Aged 0-9 years	
Regimen	**% age**
ABC+3TC+DTG+DRV+RTV	59.6%
DRV+RTV+ETV	11.5%
DRV+RTV+DTG+ETV	7.7%
ABC+3TC+DRV+RTV	5.8%
ABC+3TC+RAL+DRV+RTV	5.8%
AZT+3TC+DTG	4.8%
AZT+3TC+DRV+RTV	2.9%
AZT+3TC+RAL+DRV+RTV	1.9%
Grand Total	**100%**

All the estimates are as of December 2023 and subject to change as the program evolves subject to introduction of new molecules such as Dolutegravir/Emtricitabine/Tenofovir alafenamide 50/200/25mg (TAF/FTC/DTG), Darunavir/Ritonavir 400/50mg (DRV/r 400/50mg) FDC, and ABC/3TC/DTG 60/30/5mg in 2024.

2.2 Epidemiology data: TB

The country has had a steady reduction of TB notifications for the past 10 years from 210/100,000 in 2010 to 198/100,000 in 2022[7]. The number of TB related deaths were also on a decreasing trend from 23,000 in 2016 to 12,000 in 2021[8]. TB case notification in Uganda is strong with 82% of TB incidences notified[9]. Uganda is now among top 30 countries with highest TB burden in the world (20th of 115 Global Fund eligible countries)[10]. Although the indicator "Number of people in contact with TB patients who began preventive therapy" is performing well, it is affected by 1) delays in enrolment of identified contacts, 2) data recording and reporting issues including unclear instructions related to the use of the multiple data source documents at facility level.

2.2.1 Breakdown of Patient Numbers by Treatment Class and Regimen

The TB program achieved a notification of 94,433 cases in 2022. For first line treatment among adults, the existing 6-month regimen (2RHZE/4RH) was maintained by the TB Program in 2023 in preference to the new WHO recommended 4-month regimen (2HPMZ/2HPM) due to the high cost of the latter, not to mention the pill burden. Treatment for pediatric patients was adjusted to accommodate the roll out of the four-month (2RHZ+/2RH) regimen by 2024 for non-severe disease. For DR TB treatment, the 9-month modified short treatment regimen (mSTR) was the standard regimen having 71% of DR TB patients enrolled per year. However, in the subsequent years it is expected to be tapped down in favor of the new 2022 WHO recommended BPALM to be provided for just 6 months.

[7]https://data.worldbank.org/indicator/SH.TBS.INCD?locations=UG

[8]World TB report 2022

[9]GF OIG Report – Global Fund Grants to the Republic of Uganda (November 2023)

[10]GF OIG Report – Global Fund Grants to the Republic of Uganda (November 2023)

Table 8: 2022 TB Baseline numbers and NSP Targets

Country targets-NSP	2022-Baseline	2023	2024	% Increase in 2024
Total notifications all forms	94,433	90,810	93,392	3%
Total Targeted for TPT (HIV neg)	133,896	102,095	243,692	139%
Under 5s targets for IPT	31,317	28,364	39,691	40%
TB preventive therapy in adult contacts	102,579	73,731	204,001	177%
Number of RR/MDR-TB cases notified that are enrolled on treatment with GF allocation	761	954	871	-9%

Source: Integrated Quantification Report 23/24 FY

Table 9: Breakdown of TB Numbers by Patient category

Categories	Proportion	2023	2024	% Increase in 2024
Total notifications all forms		90,810	93,392	3%
Pediatric cases -15% of total notifications	15%	13,622	14,009	3%
Adults	85%	77,189	79,384	3%
Pediatric cases (25kgs and less)-ped formulations-2RHZ+E/4RH pediatric; 73% of pediatric cases	73%	9,944	10,226	3%
Pediatric cases that will take adult formulation	27%	3,678	3,782	3%
Adult cases equivalent of children requiring adult formulation		1,839	1,891	3%
Cases to be treated with adult formulations of 2RHZE/4RH (27% children plus all adults)		79,027	81,275	3%
Number of Patients to be enrolled on Rifabutin	PLHIV on PIs (2.2%) and 20% reach	70	324	363%
Total number of patients- quanTB		88,971	91,501	3%
Number of RR/MDR-TB cases notified that are enrolled on treatment		954	871	-9%

Source: Integrated Quantification Report 23/24 FY

Despite the national program retaining the 9-month modified short treatment regimen (mSTR) for DR TB treatment, with the regimen having 71% of patients enrolled in 2022. Transition to the new 2022 WHO recommended BPALM is expected to commence in 2024 with 75% of Second Line Patients being optimized on the 6-month regimen by 2026 as detailed in Table 10 below.

Table 10: Breakdown of Second Line TB Numbers

Categories	2022	2023	2024 Projection	% Increase from 2023	2026 Outlook Upon Transition
1. 2022 WHO recommended shorter regimen-BPALM: 6BdqLzdMfxPa	0%	0%	15%	15%	75%
2. Uganda Pediatric DR TB regimen->6yrs 9Bdq CfzCs LfxLzdPyr-B6	1%	1%	1%	0%	5%
3. Uganda_ Fluoroquinolone Resistance Regimen with Pyridoxine - All salvage items: 20BdqCfzCsDlmEtoLzdPyr-B6	7%	9%	3%	-6%	2%
4. Uganda_i_ New LTR BDQ with Pyridoxine - Updated guideline May2019: 20BdqCfzCsLfxLzdPyr-B6Z	21%	13%	16%	3%	19%
5. Uganda_j_New STR ModifiedLfx corrected- Updated guideline May2019: 9BdqCfzCsLfxLzdPyr-B6	71%	76%	64%	-12%	0%
6. Uganda_k_Peadiatric DR-TB regimen: 6CfzCs DlmLfxLzd(600)/14Cfz(50)Cs LfxLzd	0%	1%	1%	0%	1%

Source: Integrated Quantification Report 23/24 FY

2.3 Epidemiology data: HCV

The WHO Hepatitis global report 2024 estimates total hepatitis C infections (all ages) in Uganda at 356,043; Hepatitis C incidence at 5,678; Number of deaths caused by hepatitis C infection at 723; Diagnosis coverage (total), end 2022 at 9%; Treatment coverage, (of all infected), end 2022 at 0%
The prevalence of chronic HCV (RNA+/cAg) in Uganda is 0.75% (2022), and the prevalence of chronic HCV (RNA+/cAg) among persons who inject drugs is 20.6% (2017).[11]

2.4 Epidemiology data: Cervical Cancer

Current estimates by ICO/IARC Information Centre on HPV and Cancer indicate that, approximately 6,959 women in Uganda are diagnosed with cervical cancer annually, and 4,607 succumb to the disease. Cervical cancer is the leading cancer among women in the country and the most prevalent among those of reproductive age (15-44). It is estimated that around 3.6% of women in the general population harbor HPV-16/18 infection at any given time. Furthermore, 57% of invasive cervical cancers are attributed to HPV types 16 and 18[12].

[11]https://www.globalhep.org/data-profiles/countries/uganda

[12]Human Papillomavirus and Related Cancers, Fact Sheet 2023

3.0 LEGAL ENVIRONMENT

Uganda's legal environment for pharmaceutical products is structured to ensure that all drugs meet national and internationally accepted quality, safety and efficacy standards. The National Drug Authority (NDA) plays a crucial role in the regulation of drug registration, importation, distribution, and licensing of pharmaceuticals. The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition).

3.1 Drug Registration with the National Regulatory Authority

The National Drug Policy and Authority Act, Section 35 mandates NDA to scientifically examine any drug for purposes of ascertaining efficacy, safety and quality of a drug before registration for use in Uganda. Pharmaceutical companies must submit a detailed application dossier to the NDA in its prescribed format for product registration. Registration of a new product in Uganda is therefore a critical step towards making the medicine available for use in clinical settings. NDA has an accelerated shorter drug registration assessment timeline of 6 months for the registration of:

- WHO-prequalified and SRA products considered to be under a special category
- Vaccines and anticancer medicines

Table 11 below summarizes the timeline taken by NDA to assess Marketing Authorization applications.

Table 11: NDA Marketing Authorization assessment service delivery timelines

Regulatory Area	Action	Timeline (Working Days)
Marketing Authorization (MA)	Assessment of application and request for additional information on application for MA (Human Drugs)	18 months (396 Days)
	Assessment of application and request for additional information on application for MA (Vaccines, Anti-cancer medicines)	6 Months (132 Days)
	Special Categories	
	Regulatory Decision on MA for domestically manufactured products (Herbal, Conventional)	6 Months (132 Days)
	Regulatory Decision on products already authorized for marketing by Stringent Regulatory Authorities, WHO Prequalified Products, and those approved under Article 58 of EU regulations	6 Months (132 Days)

Source: NDA Approved Service Delivery Times (SDTs) FY 2024/25 (Published May 2024)

Upon satisfactory evaluation, the NDA issues marketing authorization and registers the product, allowing it to be sold and distributed in Uganda.

3.2 Importation of Pharmaceutical Products

The importation of pharmaceutical products into Uganda is also regulated by the NDA to ensure that only safe and effective drugs enter the market.

NDA Import Permit processing: Importers must obtain an import permit from the NDA for each consignment. The permit application must include details of the product, quantity, source, and intended use in some cases. For The Global Fund (TGF), and USAID shipments, the supplier Proforma Invoices (PFIs) are submitted to the MOH-DPNM for endorsement to obtain a waiver for the statutory 2% of FOB fees to NDA. The endorsed PFIs will be attached to an application for verified PFI/Import Permit and uploaded into the National Drug Authority Management Information System (NDAMIS) for approval and acquisition of an import permit.

Locally unregistered Medicines: Locally unregistered medicines can be imported with import permits processed under extraordinary circumstances especially where there are no locally registered alternatives for the molecule or formulation. The processing of permits may however take longer as applicants may be required to submit justification for such imports, or cGMP certificates from SRA or WHO prequalification.

Quality Assurance: The NDA conducts quality checks on imported pharmaceuticals at ports of entry, including laboratory testing of samples from each batch for a few products.

3.3 NDA Registered Medicines

As of July 2024 (at the time of writing this report), according to the June 2024 NDA Register, there were 74 Marketing Authorizations (MAs) for drugs in the National Treatment Guideline (NTG) for the treatment and prevention of HIV infections, 133 MAs for TB drugs, and only 4 MAs for drugs used in the management of HCV in Uganda. The following medicines in the register were only from proprietary brands;

- Cabotegravir 600 mg/3 mL vial, Prolonged-release Suspension for Injection for PrEP
- Lopinavir/Ritonavir 80mg/20mg oral liquid
- Bedaquiline 100 mg Uncoated tablet for management of MDR TB
- Sofosbuvir (400 mg)/Velpatasvir (100 mg) for management of HCV

Table 12: NDA Registered Medicines for HIV, TB, and HCV

Generic Name	No. MA Holders	Generic Name	No. MA Holders
Medicines for HIV			
Adult Formulations			
Abacavir/Lamivudine 600/300mg	4	Ritonavir 100mg	3
Abacavir/Lamivudine/Dolutegravir 600/300/50mg	3	Tenofovir Alafenamide Fumarate/Emtricitabine 25/200mg	2
Atazanavir/Ritonavir 300/100mg	4	Tenofovir Alafenamide Fumarate/Emtricitabine/ Dolutegravir 25/200/50mg	3
Zidovudine/Lamivudine 300/150mg	4	Tenofovir Disoproxil Fumarate/Lamivudine 300/300mg	5
Cabotegravir 600 mg/3 mL vial, Prolonged-release Suspension for Injection	1*	Tenofovir Disoproxil Fumarate/Lamivudine/ Dolutegravir 300/300/50mg	9
Darunavir 600mg	3	Tenofovir Disoproxil Fumarate/Lamivudine/ Efavirenz 300/300/400mg	4
Dolutegravir 50mg	9	Tenofovir Disoproxil Fumarate/Emtricitabine 300/200mg	7
Efavirenz 400mg	1		
Pediatric Formulations			
Abacavir/Lamivudine 120/60mg	2	Lopinavir/Ritonavir 100/25mg	5
Zidovudine/Lamivudine 60/30mg	1	Lopinavir/Ritonavir 80/20mg	1*
Dolutegravir 10mg	3		
Medicines for TB			
Adult Formulations			
Isoniazid 100 mg Dispersible tablet(s) Blister(s) 100	2	Pyrazinamide 500 mg Uncoated tablet(s) Blister(s) 672	1
Isoniazid 300 mg Uncoated tablet(s) Blister(s) 672	4	Rifampicin 300 mg Capsule(s) Blister(s) 100	1
Rifampicin/Isoniazid 150 mg/75 mg Film coatedtablet(s) Blister(s) 672	3	Levofloxacin 250 mg Film coated tablet(s) Blister(s) 100	4
Rifampicin/Isoniazid 75 mg/50 mg Dispersible tablet(s) Blisters(s) 84	2	Levofloxacin 500 mg Film coated tablet(s) Blister(s) 100	24
Rifapentine/Isoniazid 300mg/300mg Film coated tablet(s), Blister(s) 36	1	Levofloxacin 750 mg Film coated tablet(s) Blister(s) 100	9
Rifampicin/Isoniazid 150 mg/75 mg Film coated tablet(s) Blister(s) 672	3	Moxifloxacin 400 mg Film coated tablet(s)Blister(s) 100	14
Rifampicin/Isoniazid/Ethambutol 150 mg/75 mg/275 mg Film coated tablet(s) Blister(s) 672	2	Amikacin 500 mg/2 ml Solution for injection Ampoules 100	5
Rifampicin/Isoniazid/Pyrazinamide/Ethambutol 150 mg/75 mg/400 mg/ 275 mg Film coated tablet(s) Blister(s) 672	2	Streptomycin 1g Powder for injection-IM	2
Amoxicillin/Clavulanic acid 500 mg/125 mg Film coated tablet(s) Blister(s) 100	25	Imipenem/Cilastatin 500 mg/500 mg Powder for injection Vial(s) 10	5
Bedaquiline 100 mg Uncoated tablet(s) HDPE container(s) 188	1*	Meropenem 1 g Powder for injection Vial(s) 10	8
Bedaquiline 100mg Uncoated tablet(s) Blister(s) 100	1*	Pretomanid, 200 mg, Tablet(s), Bottle 26	1
Pediatric Formulations			
Ethambutol 100 mg Dispersible tablet(s) Blister(s) 100	1	Rifampicin/Isoniazid 75 mg/50 mg Dispersible tablet(s) Blisters(s) 84	1
Isoniazid 100 mg Dispersible tablet(s) Blister(s) 100	2	Rifampicin/Isoniazid/ Pyrazinamide 75 mg/50 mg/150 mg Dispersible tablet(s) Blister(s) 84	1
Linezolid 150 mg Dispersible tablet(s) Blister(s) 100	2		
Medicines for HCV			
Sofosbuvir (400 mg)/Velpatasvir (100 mg)	1*	Sofosbuvir 400 mg Tablet	2
Sofosbuvir (400mg)/Daclatasvir (60mg)	1	Sofosbuvir/daclatasvir	1

*The only Marketing Authorization Holder on the NDA register is the proprietary manufacturer.

The regimens in Table 13 below have no NDA registered manufacturers despite being in the National Treatment Guideline and Essential Medicines List.

Table 13: Medicines for HIV, TB, and HCV in the NTG but not on the NDA Register

Generic Name	Generic Name
Medicines for HIV	
Dapivirine 25mg, vaginal ring	Tenofovir Alafenamide Fumarate/Lamivudine/Efavirenz 25/200/400mg
Darunavir (DRV) 150mg	Abacavir/Lamivudine/Dolutegravir 60/30/5mg
Raltegravir 100mg	Lopinavir/Ritonavir 40/10mg (Oral Pellets)
Raltegravir 400mg	Ritonavir 25mg
Medicines for TB	
Pyrazinamide 400 mg Uncoated tablet(s) Blister(s) 672	Delamanid 50 mg Film coated tablet(s) Blister(s) 48
Rifabutin 150 mg Capsule(s) HDPE jar(s) 100	PAS Sodium Salt 4 g Powder Sachet 25
Rifampicin 150 mg Capsule(s) Blister(s) 100	Clofazimine 50 mg Film coated tablet(s) Blister(s) 100
Rifapentine 150 mg Film coated tablet(s) Blister(s) 24	Cycloserine 125 mg Capsule(s) Blister(s) 100
Rifapentine 300mg Film coated tablet(s) Strip(s) 100	Delamanid 25 mg Dispersible tablet (s) Blister(s) 48
Clofazimine 100 mg Capsule(s) HDPE jar(s) 100	Ethionamide 125 mg Dispersible tablet(s) Blister(s) 100
Clofazimine 50 mg Film coated tablet(s) Blister(s) 100	Levofloxacin 100 mg Dispersible tablet(s) Blister(s) 100
Ethionamide 250 mg Film coated tablet(s) Blister(s) 100	Moxifloxacin 100 mg Dispersible tablet(s) Blister(s) 100
Prothionamide 250 mg Film coated tablet(s) Blister(s) 100	Pyrazinamide 150 mg Dispersible tablet(s) Blister(s) 100
Terizidone 250 mg Capsule(s) Blister(s) 100	Rifapentine 150 mg Dispersible tablet(s) Blister(s) 100
Medicines for HCV	
Ribavirin 200mg, 400mg, 500mg, 600mg Tablet	sofosbuvir (400 mg)/ledipasvir (90 mg)

The Ministry of Health of the Republic of Uganda procures drugs included in the Essential Medicines and Health Supplies List (EMHSLU), as well as indicated in the National Treatment Guideline (NTG) for a particular disease or condition regardless of their NDA registration status. Import permits may be processed under extraordinary circumstances i.e., a consignment of drugs for donation or a consignment imported by or for a government ministry, department, project or program. However, manufacturers are encouraged to register their products as non-registration can complicate drug importation especially in private sector where registered alternatives of such drugs exist.

3.4 Tax Regime

Medicines for HIV, TB, HCV, and Cervical cancer are tax exempt except for the mandatory 2% of Free On Board (FOB) charge for import verification paid by private players.

4.0 ESSENTIAL MEDICINES AND HEALTH SUPPLIES LIST FOR UGANDA (EMHSLU), NATIONAL TREATMENT GUIDELINES, AND WHO GUIDELINES

4.1 Essential Medicines List

The Essential Medicines and Health Supplies List for Uganda (EMHSLU) reflects the policy of the Ministry of Health, for the appropriate procurement of safe and efficacious essential medicines, health and laboratory supplies in public institutions. Items are categorized by the level of care to promote availability of medicines at all levels, and by the Vital, Essential and Necessary (VEN) classification. The VEN system prioritizes items according to health impact, to ensure that adequate stock levels of life-saving medicines and health supplies at the facility will always be available, leading to better healthcare services. The EMHSLU 2023 was compiled based on recommendations from various categories of health workers at the Ministry of Health and from health facilities. It was updated in conjunction with the Uganda Clinical Guidelines (UCG) 2023, to ensure that all essential medicines, health and laboratory supplies needed to treat common conditions according to the UCG are included. The medicines list is classified by therapeutic categories, following the 22nd edition of the World Health Organization (WHO) model list (2021), and contains both the general and specialist medicines in one list for ease of reference.

It is the hope of the Ministry of Health that the updated essential medicines and health supplies list will be used by providers in both the public and private sectors, to guide, ensure availability and use of quality, safe, efficacious and cost-effective medicines, health and laboratory supplies in Uganda. The National Medical Stores (NMS) that is mandated with the procurement of all essential medicines for and on behalf of Government of Uganda, procures in line with the Essential Medicine List of Uganda except in cases of support for special MoH requests.

The EMHSLU 2023 follows the 2016 edition. Updating was guided by a user survey that highlighted the usefulness, challenges and scope of the guidelines. This was followed by consultations from multiple stakeholders, to ensure comprehensive reviews, and was based on principles of clinical evidence-based medicine, cost-effectiveness, current WHO guidelines and Ministry of Health policies. Users are encouraged to document and submit any recommendations that can improve future guidelines to the Ministry of Health.

Table 14 below summarizes HIV and TB drugs in the EMHSLU 2023

Table 14: HIV and TB drugs in the EMHSLU 2023

Generic Name	Dosage Form	Strength
Antiretrovirals		
4.2.1 Nucleoside/ Nucleotide reverse transcriptase inhibitors		
Tenofovir	Tablet	300 mg
4.2.2 Non-nucleoside reverse transcriptase inhibitors		
Nevirapine	Suspension	10 mg/ml
Dapivirine	Vaginal Ring	25mg
Efavirenz	Tablet	200mg
Etravirine	Tablet	100 mg
Etravirine	Tablet	25 mg
4.2.3 Protease inhibitors		
Atazanavir + (ritonavir)	Tablet	300 mg+ (100mg)
Darunavir + (Ritonavir)	Tablet	75 mg + (100 mg)
Darunavir (+Ritonavir)	Tablet	600 mg + (100mg)
Darunavir (+Ritonavir)	Tablet	400 mg + (50mg)
Ritonavir	Tablet	25 mg
Lopinavir (+ Ritonavir)	granules/Sachets	40 mg + 10 mg/ml
Lopinavir (+ ritonavir)	Tablet	100 mg + 25 Mg
Lopinavir (+ Ritonavir)	Tablet	200 mg + 50 Mg
Ritonavir	Tablet	100 mg
4.2.4 Fixed dose combinations		
Abacavir + Lamivudine	Tablet (dispersible)	120 mg + 60 Mg
Abacavir + Lamivudine	Tablet	600 mg + 300 mg
Tenofovir+ Lamivudine	Tablet	300 mg + 300 mg
Tenofovir + Emtricitabine	Tablet	300mg + 200mg
Zidovudine + Lamivudine	Tablet	300 mg + 150 mg
Zidovudine +Lamivudine	Tablet	60 mg + 30mg
Tenofovir + Lamivudine + Efavirenz	Tablet	300mg +300mg +400mg
Abacavir + Lamivudine + Dolutegravir	Tablet	600mg + 300mg +50mg
Abacavir + Lamivudine + Dolutegravir	Tablet	60mg + 30mg + 5mg
Tenofovir + Lamivudine+Dolutegravir	Tablet	300mg + 300mg + 50mg
Tenofovir Alafenamide + Emtricitabine + Dolutegravir	Tablet	25mg + 200mg + 50mg
4.2.5 Integrase inhibitors		
Raltegravir	Tablet (chewable)	100 mg
Raltegravir	Tablet	400 mg
Dolutegravir	Tablet	50 mg
Doultegravir	Tablet	10mg
Cabotegravir	Injectable	600mg/3ml
4.2.2 Anti tuberculosis medicines		
Ethambutol	Tablet	400 mg
Ethambutol	Tablet	100 mg
Isoniazid	Tablet	300 mg
Isoniazid	Tablet (Dispersible)	100 mg
Pyrazinamide	Tablet	400 mg
Rifampicin + Isoniazid	Dispersible tablet	60 mg + 30 mg
Rifampicin + Isoniazid	Tablet	150 mg + 75 mg
Rifampicin + Isoniazid	Tablet	300 mg + 150 mg
Rifampicin+ Isoniazid + Pyrazinamide	Tablet	60 mg + 30 mg + 150 mg
Rifampicin + Isoniazid + Pyrazinamide + Ethambutol	Tablet	150 mg + 75 mg + 400 mg + 275 mg
Rifabutin	Capsule	150 mg
Rifampicin + Isoniazid + Pyrazinamide	Tablet	75mg + 50 mg + 150 mg
Rifapentine +Isoniazid	Tablet	300mg +300mg
Rifapentine	Tablet	150mg
Rifampicin + Isoniazid	Dispersible tablet	75 mg + 50 mg
Delamanid	Tablet	50mg
Delamanid	Tablet	25mg
Bedaquiline	Tablet	100 mg
Bedaquiline	Tablet	20mg
Cycloserine	Capsule	250 mg
Cycloserine	Tablet	125mg
Ethionamide	Tablet	250 mg, 125 mg
Levofloxacin	Tablet	250 mg
Levofloxacin	Tablet	100mg
Linezolid	Tablet	100 mg
Generic Name	**Dosage Form**	**Strength**
Prothionamide	Tablet	250 mg
Clofazimine	Capsule	100 mg
Levofloxacin	Tablet	100mg
Clofazimine	Tablet	50mg

4.2 Drugs not in the Essential Medicines List

None of the HCV Direct Acting Antivirals (DAA) in the Uganda Guidelines for Prevention, Testing, Care and Treatment of Hepatitis B and C Virus Infection, November 2019 is in the EMHSLU 2023. Below is a summary of all regimens in the national treatment guideline missing in the Essential Medicines List.

Table 15: HCV DAA in Treatment Guideline, 2019 missing in the EMHSLU 2023

Sofosbuvir(400mg)/Velpatasvir(100mg)	Sofosbuvir (400 mg)/Ledipasvir (90mg)	Ribavirin 200mg, 400mg, 500mg, 600mg Tablet
Sofosbuvir(400mg)/Daclatasvir(60mg)	Sofosbuvir 100mg, 400 mg Tablet	

For TB, Pretomanid 200 mg Tablet that is an import molecule in the BPaLM regimen, a newly recommended WHO combination for MDR/RR-TB, the regimen comprises bedaquiline (B), pretomanid (Pa), linezolid (L) and moxifloxacin (M), is also missing in the most recent list of essential medicines. The country has planned commencement of transition to BPaLM in 2024 to be the regimen of choice in MDR patients by 2026 being administered to 75% of MDR patients.

4.3 WHO Guidelines

4.3.1 WHO recommendations for HIV

WHO recommendations for HIV have been adopted by Uganda, 97% of first line PLHIV on treatment and 86% of second line PLHIV have been optimized on WHO recommended Dolutegravir based regimens.

The AIDS Control Program (ACP) has also adopted new HIV prevention interventions. 5% (13,000) of the PrEP target for 2024 (230,000) is set to be achieved through newly introduced WHO recommended regimens i.e., Injectable cabotegravir (LA-CAB) 600 mg/3ml Inj (80% of the 5% PrEP Target) and Dapivirine vaginal ring (20% of the 5% PrEP Target).

The country is yet to adopt other newly emerging molecules i.e., long-acting injectable Cabotegravir/ Rilpivirine (LA CAB/RPV) and Lenacapavir 309 mg/mL[13] sub-cutaneous injection that are USFDA approved (high-income country) but are currently not recommended by the WHO. The twice-a year administered Lenacapavir demonstrated 100% Efficacy and Superiority to existing regimens for HIV Prevention from results of a Phase 3, PURPOSE 1 Trial in Uganda and South Africa.[14]

4.3.2 WHO Recommendation for HCV

The Uganda Guidelines for Prevention, Testing, Care and Treatment of Hepatitis B and C Virus Infection was last updated in 2019. There is need to update the national guidelines to bring them in full compliance with WHO updated recommendations on treatment of adolescents and children with chronic HCV infection, and HCV simplified service delivery and diagnostics in 2022.

[13]On December 22, 2022, the FDA announced the approval of Gilead Sciences' Sunlenca (lenacapavir), in combination with other antiretroviral(s), for the treatment of human immunodeficiency virus (HIV)-1 infection in heavily treatment-experienced adults with multi-drug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations

[14]https://www.gilead.com/news-and-press/press-room/press-releases/2024/6/gileads-twiceyearly-lenacapavir-demonstrated-100-efficacy-and-superiority-to-daily-truvada-for-hiv-prevention

The current guidelines do not address the following recommendations from the WHO:

- For children aged less than 12 years with chronic hepatitis C, the current national guideline (2019) recommends deferring treatment until 12 years of age in those without cirrhosis or with only compensated cirrhosis. The 2022 updated WHO guidelines lower treatment age to those between 3 to 12 years of age i.e., older children (6–11years) (all strong recommendation) and younger children (3–5 years) (conditional recommendation)[15]. At the time of the 2018 WHO HCV guidelines, none of the recommended pangenotypic DAAs for adults (sofosbuvir/daclatasvir, sofosbuvir/velpatasvir, glecaprevir/pibrentasvir) had been approved for use in either adolescents or children. Therefore, WHO recommended use of two non-pangenotypic DAA regimens (sofosbuvir/ledipasvir and sofosbuvir/ribavirin) that had received regulatory approval from the FDA and the EMA for use in adolescents (≥12 years) but advised deferral of treatment in those under 12 years of age until DAA regimens become available for these younger age groups. However, given the 2022 WHO updates, the national guidelines equally require an update.
- Glecaprevir/Pibrentasvir [Glecaprevir 300 mg/Pibrentasvir 120 mg] a shorter 8-week regimen has been introduced as an alternative to the 12-week course of Sofosbuvir/Daclatasvir (most widely used) and Sofosbuvir/Velpatasvir
- The national guideline has the following regimens for use in adolescents aged 12–17 years or weighing at least 35 kg with chronic HCV infection, use: sofosbuvir/ledipasvir for 12 weeks in genotypes 1, 4, 5 and 6, sofosbuvir/ribavirin for 12 weeks in genotype 2 and 24 weeks in genotype 3. Sofosbuvir/Ribavirin was not retained in the updated WHO recommendation. Ribavirin requires hematological monitoring and is teratogenic hence its replacement.

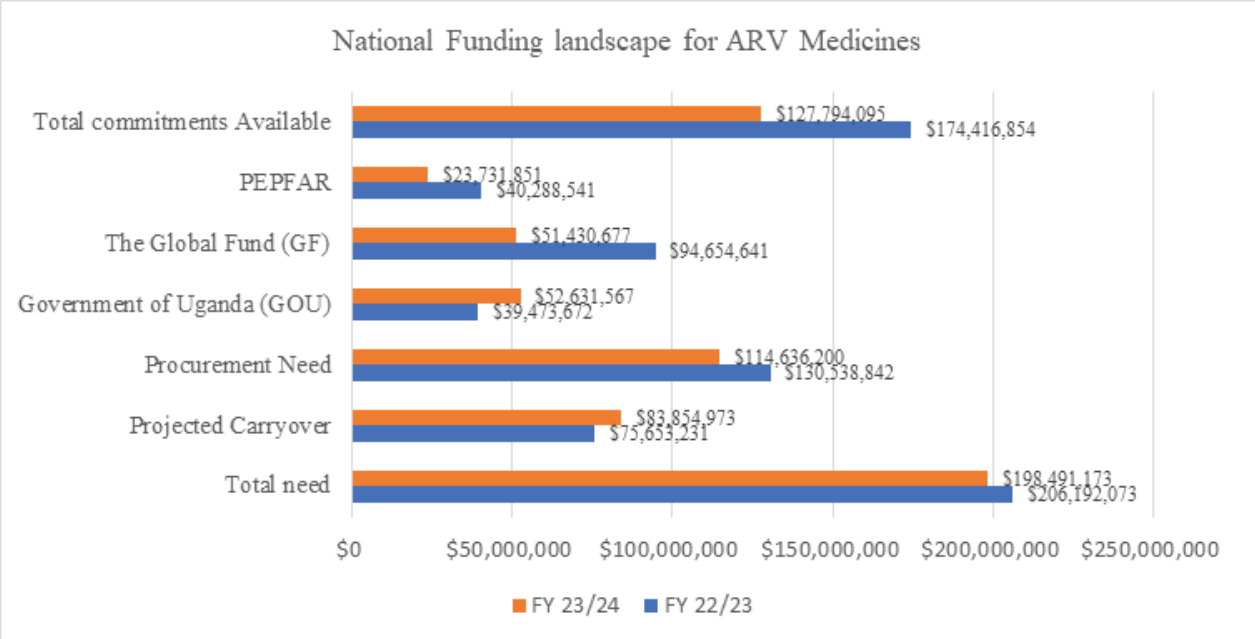
[15]Updated Recommendations on Treatment of Adolescents and Children with Chronic HCV Infection, and HCV Simplified Service Delivery and Diagnostics

5.0 BUDGETS, PROCUREMENT MECHANISMS, VOLUMES AND STRUCTURE OF PROCUREMENT

5.1 National Budget for HIV Medicines

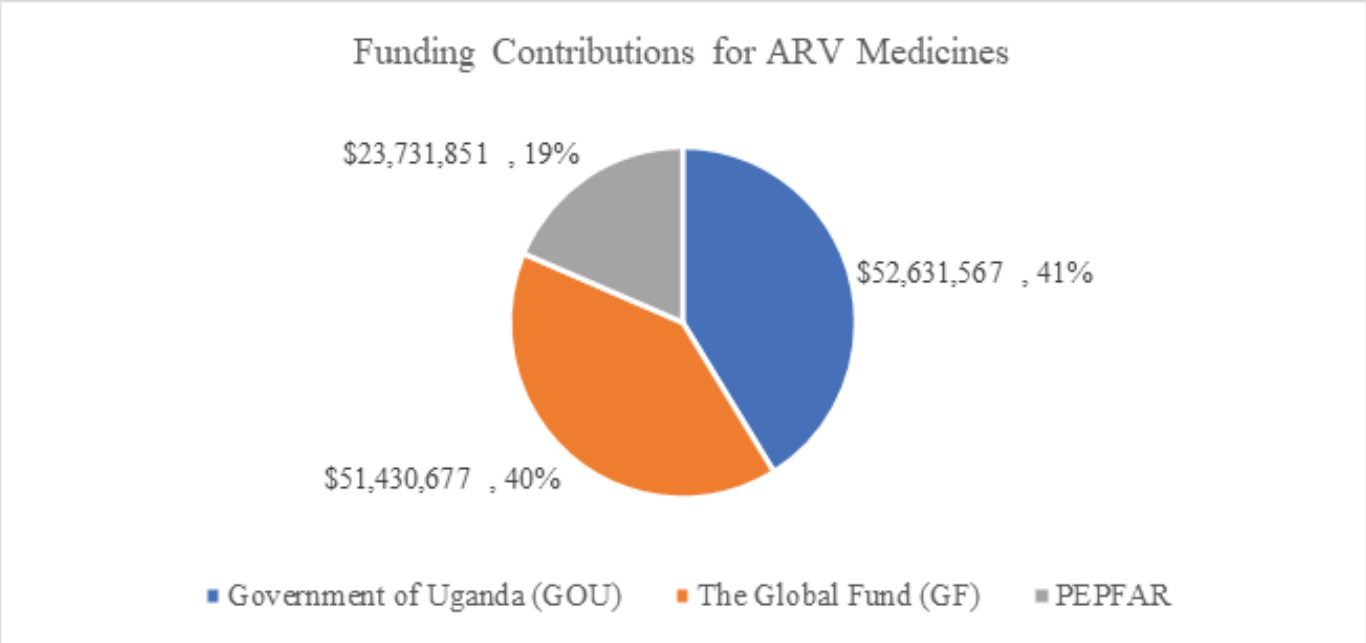
With reference to the Integrated Forecast Report 2023, for FY 23/24 and FY 24/25, there is no funding gap for HIV Medicines. This is because of a significant carryover of stock from FY 22/23, adequate funding commitments from Government of Uganda (GoU), GF and PEPFAR. There was a funding gap for the FY 24/25 attributed to no confirmed commitments yet from PEPFAR at the time of the forecast report in May 2023. However, no actual gap is expected upon COP approval. GOU funding increased from $ 39,473,672 to $ 52,631,567 (33% increase). This GoU funding increment is partly responsible for no funding gap in the public sector starting FY 23/24 to FY 24/25.

Figure 1: National Funding Landscape for ARV Medicines for FY 23/24



Source: Integrated Quantification Report for Essential Medicines and Health Supplies (May 2023)

Figure 2: Funding Contribution by Partner for HIV Treatment Commodities for FY 23/24



The GOU money is used to procure 5 commodities i.e.,1) Abacavir/Lamivudine 600/300mg 2) Zidovudine/Lamivudine 300/150mg 3) Tenofovir Disoproxil Fumarate/Lamivudine/ Dolutegravir 300/300/50mg 4) Tenofovir Disoproxil Fumarate/Lamivudine/ Efavirenz 300/300/400mg 5) Tenofovir Disoproxil Fumarate/Lamivudine 300/300mg that are largely sourced from a WHO approved local manufacturer. From budget contributions for FY 23/24, 59% (USD 75M) are spent on ARV drugs procured from international sources by donor agencies.

5.2 National Budget for TB Medicines

Significant commitments in funding for first- and second-line anti-TB medicines from Government of Uganda and The Global Fund has enabled full funding for the FY23/24. The previous year FY 22/23 had a funding gap of USD 31,583 (<1% of Total commitment).

Figure 3: Overall analysis of the funding for TB treatment commodities

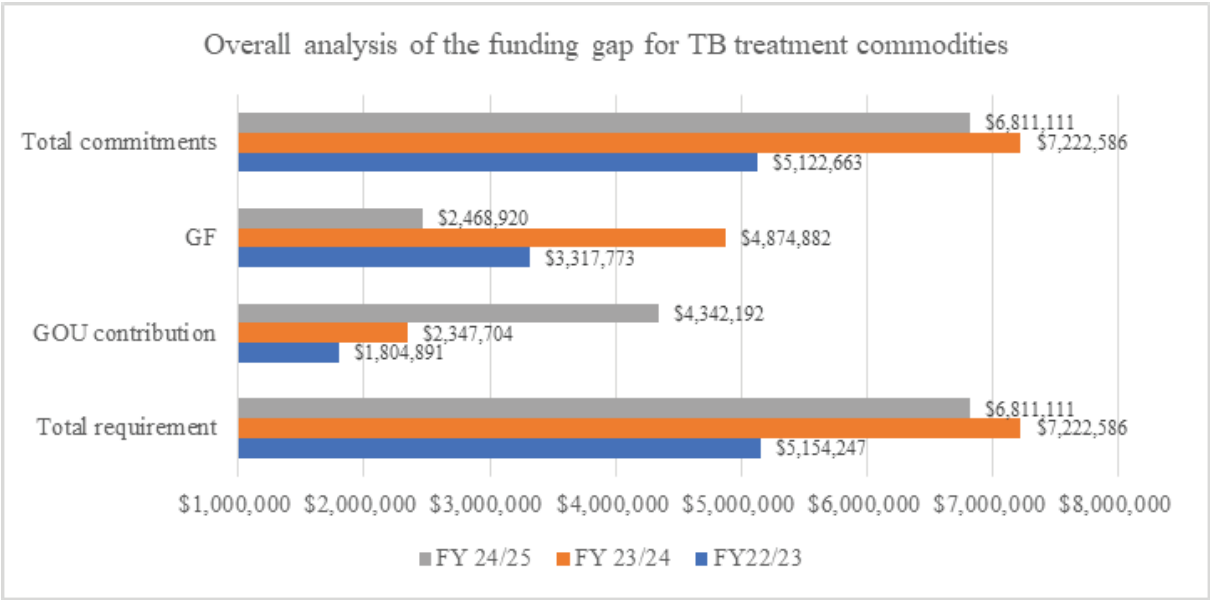
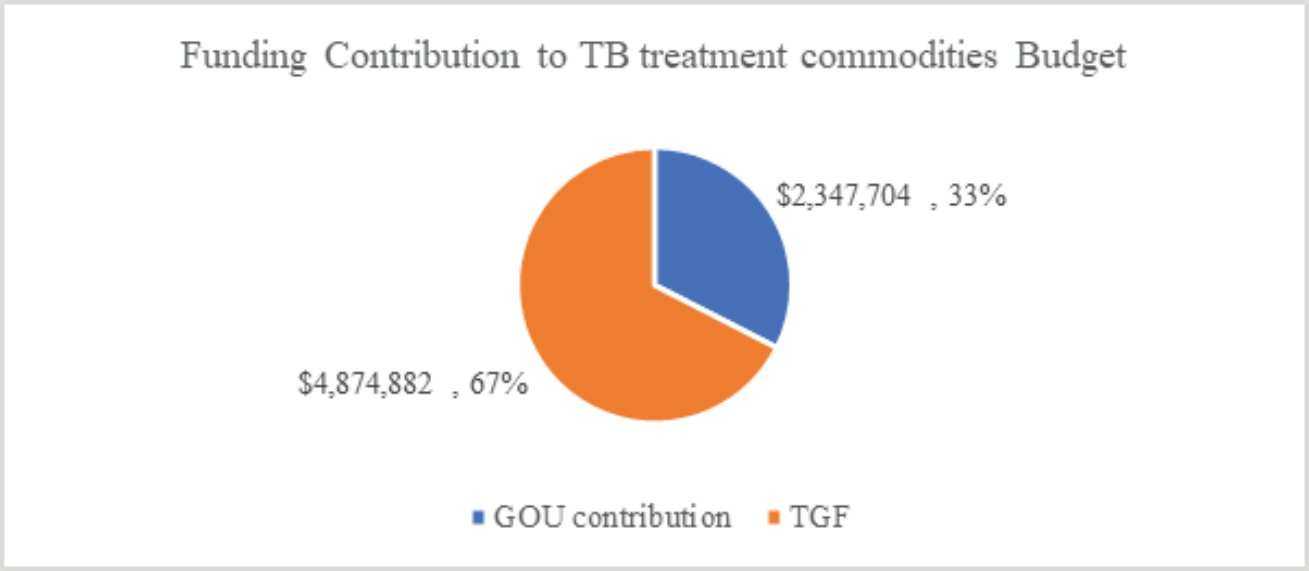


Figure 4: Funding Contributions for TB Treatment for FY 23/24



The study team was not able to locate such detailed funding data for HCV and Cervical Cancer.

Key takeaways

- Global Fund is the main external donor for TB and HIV Treatment Commodities. PEPFAR is a significant donor in HIV Treatment commodities.
- There is no funding gap for TB and HIV Treatment commodities for FY 23/24.
- There has been significant increase in government investment in HIV and TB treatment commodities compared to previous years.
- Currently neither Government of Uganda (GOU) nor external donors support HCV commodity procurement.

5.3 Procurement Mechanisms

The MOH procures all TGF-funded commodities through Wambo (PPM) and the Global Drug Facility (GDF). The requisition is initiated by the MOH team, orders are then confirmed by PPM and GDF Team. Consignments are received at the National Medical Stores central warehouse in Entebbe (Air through Entebbe; sea bulk through ports in Kenya). PEPFAR funded commodities are procured through Joint Medical Stores (JMS) and Medical Access Uganda Limited (MAUL). Both JMS and MAUL are local entities that were awarded an Indefinite Delivery Indefinite Quantity (IDIQ) Contract to procure HIV commodities for the Private Not-For- Profit (PNFP) Sector by The United States Agency for International Development (USAID). Both procurement agencies are compliant with The WHO Model Quality Assurance System for Procurement Agencies (MQAS). Procurement is therefore expected to follow international best practices. GOU funded commodities are procured by the National Medical Stores (NMS), the entity mandated with the procurement of all essential medicine for and on behalf of Government of Uganda except for Anticancer medicines that are procured by the Uganda Cancer Institute. Most NMS contracts for ARVs are with Cipla Quality Chemicals Limited, the local WHO approved manufacturer as government pushes the local/regional manufacturing strategy. An ambition that is in line with PEPFAR's five-year strategy i.e., to improve regional self-reliance and ensure a sustainable HIV commodity supply, shorten the pipeline, and build resilience to supply chain disruptions.

HCV DAAs are neither funded by GOU nor any donor. NMS supplies medicines and medical supplies that are in line with the Essential Medicine List of Uganda except in cases of support for special MoH requests. The HCV DAAs not being on the EMHSLU are not supplied by NMS. A telephone engagement with Pharmacists at 3 regional referral hospitals indicated that though Hepatitis B Virus (HBV) medicines that are in the EMHSLU are supplied by NMS, HCV medicines that are not in the EMHSLU can only be accessed by patients in the private sector out of pocket.

5.4 Volume and structure of procurement

Because of the significant stock carryover estimated at USD 75M from FY 22/23 procured in 2022 as shown in section 5.1, an assumption was made that the volume of all drugs delivered in 2023 represent the volume of 2023 procurements. Given that 97% of first line PLHIV on treatment and 86% of second line PLHIV have been optimized on Dolutegravir based regimens. A significant amount of patient courses procured in 2023 are for DTG based formulations (~81%). All products are sourced from generic manufacturers except for 1) LPV/r 80/20mg syrup from AbbVie, 2) Raltegravir 100mg chewable tablets from Merck Sharp & Dohme, and recently 3) Cabotegravir 600 mg/3 mL vial, Prolonged-release Suspension for Injection from ViiV Healthcare Pty Ltd, and potentially 4) Dapivirine 25mg, vaginal ring to be sourced in 2024 from International Partnership for Microbicides.

Table 16: Volume of HIV Treatment Commodities delivered in 2023.

Item Description	Pack Size	Number of packs	Proportion as a % of Volume Delivered
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets	90	10,160,827	62%
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets	30	2,078,037	13%
Abacavir/Lamivudine 120/60 mg [UG] Tablet, 30 Tablets	30	1,114,097	7%
Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets	30	777,010	5%
Dolutegravir 10 mg Scored Dispersible Tablet, 90 Tablets	90	465,986	3%
Dolutegravir 50 mg Tablet, 30 Tablets	30	297,798	2%
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets	60	278,146	2%
Dolutegravir/Abacavir/Lamivudine 50/600/300 mg Tablet, 30 Tablets	30	228,771	1%
Nevirapine 10 mg/mL Suspension, 100 mL	100mL	207,483	1%
Lopinavir/Ritonavir 100/25 mg Tablet, 60 Tablets	60	176,395	1%
Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets	30	132,260	1%
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	30	118,182	1%
Lamivudine/Zidovudine 30/60 mg Tablet, 60 Tablets	60	109,934	1%
Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 90 Tablets	90	55,244	0.34%
Ritonavir 100 mg Tablet, 60 Tablets	60	48,772	0.30%
Abacavir/Lamivudine 600/300 mgTablet, 30	30	35,962	0.22%
Darunavir 600 mg Tablet, 60 Tablets	60	31,331	0.19%
Lopinavir/Ritonavir 200/50 mg Tablet, 120 Tablets	120	17,661	0.11%
Raltegravir 400 mg Tablet, 60 Tablets	60	6,067	0.04%
Etravirine 100 mg Tablet, 120 Tablets	120	4,375	0.03%
Ritonavir 25 mg Tablet, 60 Tablets	60	1,408	0.01%
Darunavir 150 mg Tablet, 240 Tablets	240	1,352	0.01%
Darunavir 75 mg Tablet, 480 Tablets	480	0	0%
Darunavir/Ritonavir 400/50 mg Tablet, 60 Tablets	60	0	0%
Dolutegravir/Abacavir/Lamivudine 5/60/30 mg Dispersible Tablet, 180 Tablets	180	0	0%
Dolutegravir/Emtricitabine/Tenofovir AF 50/200/25 mg Tablet, 90 Tablets	90	0	0%
Efavirenz 200 mg Tablet, 90 Tablets	90	0	0%
Lopinavir/Ritonavir 40/10 mg Granule, 120 Sachets	120	0	0%
Ritonavir 100 mg Tablet, 30 Tablets	30	0	0%
Grand Total		**16,347,098**	**100%**

The first seven products make up 93% of the volume delivered by packs in 2023 and the first 13 make up 99% of the volume delivered by packs. Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet makes up 75% of the delivered volume by packs, Abacavir/Lamivudine 120/60 mg [UG] Tablet, 30 Tablets the main anchor for pediatric dosage forms makes up 7% of the delivered volume, Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets for Pre-Exposure Prophylaxis makes up 5% of the delivered volume, Dolutegravir 10 mg Tablet, 30 Tablets for pediatrics makes up 3% of delivered volume, Dolutegravir 50 mg Tablet, 30 Tablets and Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets both make up 2% of the delivered volume. The first 13 products that make up 99% of the delivered volume are all from generic sources. Third liners where some branded products are sourced make up <0.5% of the delivered volume. In 2023, Cabotegravir 600 mg/3 mL vial, Prolonged-release Suspension for Injection, and Dapivirine 25mg, vaginal ring was not procured. These have however been planned for procurement in 2024. A donation of the two PrEP regimens were expected in 2023 but the same were never delivered, neither was it received at the time of this report in June 2024.

From reviewed data only 15% of the delivered volume in 2023 was sourced through NMS from government funding as summarized in Table 17 below.

Table 17: Delivered Volume in 2023 from Government Sourcing.

Item Description	Pack Size	Number of packs	Proportion as a % of Volume Delivered
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets	30	1,226,392	8%
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets	90 1	,118,740	7%
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets	60	151,458	1%
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	0	25,282	0.2%
Grand Total		**2,521,872**	**15%**

5.5 Drug Prices in 2023

While the first 13 products in Table 16 that make up 99% of the delivered volume are generics, the Global Fund and PEPFAR sourcing mechanisms have also been responsible for 84% of those deliveries. The decreasing price trends for these pooled procurement mechanisms have been well documented especially Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg which is the budget driver for ARV commodities in fully optimized programs like Uganda. According to the CHAI HIV Market Report 2021, adult first-line (1L) treatment cost in generic-accessible LMICs (excluding South Africa) declined by USD 4 per patient per year from USD 70 to USD 66 in 2020. Reflecting a continued drop in the price of TLD and optimization away from more expensive regimens.

Table 18 and 19 below summarize Global Fund commodity orders and prices in PQR for 2023 for HIV and TB respectively.

Table 18: ARV Order Transactions reported to the PQR in 2023.

Product	Description	Pack size	Purchase Order Number	Manufacturer	Purchase Order Date	Pack quantity	Product pack (USD)	Total Product Cost (USD)
Abacavir+Dolutegravir+Lamivudine FDC	600mg+50mg+300mg | tab	30	7502	Laurus Labs	9-Jan-23	46,886	20.00	937,720
Abacavir+Dolutegravir+Lamivudine FDC	600mg+50mg+300mg | tab	30	8231	Laurus Labs	12-Jun-23	202,065	20.00	4,041,300
Abacavir+Lamivudine - FDC	120mg+60mg | dispers tab	30	7583	Cipla Ltd	23-Jan-23	95,480	2.65	253,022
Abacavir+Lamivudine - FDC	120mg+60mg | dispers tab	30	8231	Cipla Ltd	12-Jun-23	299,530	2.65	793,755
Abacavir+Lamivudine - FDC	600mg+300mg | tab	30	8126	Hetero labs Limited	22-Jun-23	4,560	6.84	31,190
Abacavir+Lamivudine - FDC	600mg+300mg | tab	30	8126	Hetero labs Limited	22-Jun-23	8,352	6.84	57,128
Abacavir+Lamivudine - FDC	600mg+300mg | tab	30	8231	Macleods Pharmaceuticals Ltd	12-Jun-23	10,534	7.96	83,851
Atazanavir+Ritonavir - FDC	300mg+100mg | tab	30	7583	Emcure Pharmaceuticals Limited	23-Jan-23	9,360	9.90	92,664
Atazanavir+Ritonavir - FDC	300mg+100mg | tab	30	7502	Mylan Laboratories	9-Jan-23	14,100	10.95	154,395
Atazanavir+Ritonavir - FDC	300mg+100mg | tab	30	7583	Mylan Laboratories	23-Jan-23	10,950	10.95	119,903
Darunavir (TCM)	600mg | tab	60	7583	Hetero labs Limited	23-Jan-23	6,240	40.50	252,720
Darunavir (TCM)	600mg | tab	60	8231	Hetero labs Limited	12-Jun-23	16,896	40.50	684,288
Darunavir (TCM)	75mg | tab	480	8231	Janssen	12-Jun-23	111	54.00	5,994
Darunavir (TCM)	150mg | tab	240	7502	Janssen	9-Jan-23	336	54.00	18,144
Darunavir (TCM)	150mg | tab	240	8231	Janssen	12-Jun-23	1,006	54.00	54,324
Darunavir (TCM)	600mg | tab	60	7502	Mylan Laboratories	9-Jan-23	13,337	42.00	560,154
Dolutegravir (as sodium salt)	10mg | dispers tab	90	7502	Macleods Pharmaceuticals Ltd	9-Jan-23	38,181	4.30	164,178
Dolutegravir (as sodium salt)	10mg | dispers tab	90	7583	Macleods Pharmaceuticals Ltd	23-Jan-23	21,732	4.30	93,448
Dolutegravir (as sodium salt)	10mg | dispers tab	90	7583	Macleods Pharmaceuticals Ltd	23-Jan-23	37,811	4.30	162,587
Dolutegravir (as sodium salt)	10mg | dispers tab	90	8231	Macleods Pharmaceuticals Ltd	12-Jun-23	70,569	4.30	303,447
Dolutegravir (as sodium salt)	50mg | tab	30	8231	Shanghai Desano Bio-pharmaceutical Co., Ltd	12-Jun-23	77,578	1.25	96,973
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Aurobindo Pharma Ltd	14-Jun-23	500,000	9.75	4,875,000
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	7583	Cipla Ltd	23-Jan-23	498,540	8.73	4,352,254
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Emcure Pharmaceuticals Limited	14-Jun-23	586,650	9.40	5,514,510
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Lupin Ltd	14-Jun-23	586,631	9.89	5,801,781
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Macleods Pharmaceuticals Ltd	14-Jun-23	499,705	8.95	4,472,360
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Strides Pharma Science Limited	14-Jun-23	500,000	9.22	4,610,000
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	90	8245	Sun Pharmaceuticals (formerly: Ranbaxy)	14-Jun-23	500,000	11.18	5,590,000
Dolutegravir + Lamivudine + Tenofovir DF - FDC	50mg+300mg+300mg | tab	30	8126	Shanghai Desano Bio-pharmaceutical Co., Ltd	22-Jun-23	35,886	3.68	132,060
Etravirine (ETV)	100mg | tab	120	7502	Janssen	9-Jan-23	875	36.00	31,500
Etravirine (ETV)	100mg | tab	120	7583	Janssen	23-Jan-23	1,750	36.00	63,000
Etravirine (ETV)	100mg | tab	120	8231	Janssen	12-Jun-23	875	36.00	31,500
Lamivudine+Tenofovir - FDC	300mg+300mg | tab	30	7502	Mylan Laboratories	9-Jan-23	9,550	2.85	27,218
Lamivudine+Tenofovir - FDC	300mg+300mg | tab	30	8126	Mylan Laboratories	22-Jun-23	16,706	2.85	47,612

Lamivudine+Tenofovir - FDC	300mg+300mg | tab	30	8126	Mylan Laboratories	22-Jun-23	13,444	2.85	38,315
Lamivudine+Zidovudine - FDC	30mg+60mg | dispers tab	60	8231	Mylan Laboratories	12-Jun-23	33,462	1.70	56,885
Lamivudine+Zidovudine - FDC	150mg+300mg | tab	60	8126	Shanghai Desano Bio-pharmaceutical Co., Ltd	22-Jun-23	40,890	4.88	199,543
Lopinavir+Ritonavir - FDC	100mg+25mg | tab	60	8231	Aurobindo Pharma Ltd	12-Jun-23	7,000	5.50	38,500
Lopinavir+Ritonavir - FDC	100mg+25mg | tab	60	7583	Mylan Laboratories	23-Jan-23	11,712	5.50	64,416
Lopinavir+Ritonavir - FDC	200mg+50mg | tab	120	7502	Mylan Laboratories	9-Jan-23	4,318	16.20	69,952
Lopinavir+Ritonavir - FDC	200mg+50mg | tab	120	7583	Mylan Laboratories	23-Jan-23	3,125	16.20	50,625
Nevirapine (NVP)	10mg/ml | oral liquid	100	8231	Cipla Ltd	12-Jun-23	33,684	1.25	42,105
Raltegravir	400mg | tab	60	7502	Merck Sharp & Dohme Limited	9-Jan-23	1,152	55.50	63,936
Raltegravir	400mg | tab	60	7583	Merck Sharp & Dohme Limited	23-Jan-23	1,280	55.50	71,040
Ritonavir (RTV)	100mg | tab	30	7891	Hetero labs Limited	23-Mar-23	5,508	6.00	33,048
Ritonavir (RTV)	100mg | tab	30	7891	Hetero labs Limited	23-Mar-23	4,212	6.00	25,272
Ritonavir (RTV)	100mg | tab	30	7891	Hetero labs Limited	23-Mar-23	13,392	6.00	80,352
Ritonavir (RTV)	100mg | tab	30	7891	Hetero labs Limited	23-Mar-23	1,080	6.00	6,480
Ritonavir (RTV)	100mg | tab	30	8231	Hetero labs Limited	12-Jun-23	31,860	6.00	191,160
Ritonavir (RTV)	100mg | tab	30	7891	Mylan Laboratories	23-Mar-23	11,654	7.00	81,578
Ritonavir (RTV)	100mg | tab	30	7891	Mylan Laboratories	23-Mar-23	11,106	7.00	77,742
							Total	**45,700,929**

Table 19: Anti-TB Medicine Order Transactions reported to the PQR in 2023.

Product	Description	Pack Size	Purchase Order Number	Manufacturer	Purchase Order Date	Pack quantity	Product pack (USD)	Total Product Cost (USD)
Ethambutol	100mg | dispers tab	100	22211415 SQ	Macleods Pharmaceuticals Ltd	15-Feb-23	7,380	20.05	147,969
Ethambutol+Isoniazid+Pyrazinamide+Rifampicin (RHZE)- FDC	275mg+75mg+400mg+150 mg | tab	672	22211415 SQ	Macleods Pharmaceuticals Ltd	15-Feb-23	3,835	68.20	261,547
Isoniazid+Pyrazinamide+Rifampicin - FDC	50mg+150mg+75mg | dispers tab	84	22211415 SQ	Macleods Pharmaceuticals Ltd	15-Feb-23	5,928	6.28	37,228
Isoniazid+Rifampicin - FDC	50mg+75mg | dispers tab	84	22211415 SQ	Macleods Pharmaceuticals Ltd	15-Feb-23	5,253	4.75	24,952

Pricing for the government procurements could however not be obtained for analysis and comparison against the donor sourced products. None of the recent Office of the Auditor General (OAG) Reports have reported on price or value for money analysis after the 2016 report. The 2016 OAG report on NMS indicated that the local manufacturer's prices were dictated by the MoU that was signed between MoH on behalf of GoU and the manufacturer with provision for negotiations. It also provided for procurement of all ARVs from the local manufacturer (CiplaQuality Chemical Industries Limited) by government and Related Agencies. The 2016 OAG report however noted that (5) out of the eight (8) selected donor sourced drugs were on average cheaper than those of the local supplier prices. The percentage average difference for three (3) out of the five (5) drugs was found to be more than 25%. i.e., Lamivudine/Zidovudine 150/300 mg Tablet, and Lamivudine/Tenofovir DF 300/300 mg Tablet, were 13% and 28% higher than the donor price respectively.[16]

In 2024, the AIDs Control Program has introduced Cabotegravir 600 mg/3 mL vial, Prolonged-release Suspension for Injection, and Dapivirine 25mg for PrEP to be sourced through the Global Fund mechanism. The assumption for the implementation of the new regimens is summarized in Table 20-21 below.

Table 20: National PrEP Targets and Phased implementation of LA CAB

Approach		FY22/23	FY	FY 24/25	FY 25/26	Notes
Total		**180,000**	**243,000**	**256,000**	**269,000**	
Existing - TDF/FTC (Oral)	Number	180,000	230,850	230,000	230,000	Projected targets provided by ACP
	Proportion	100%	95%	90%	86%	
New Approaches	Number	0	13,000	26,000	39,000	Projected targets provided by ACP
	Proportion	0%	5%	10%	14%	

Source: Integrated Quantification Report 23/24 FY

Table 21: Disaggregation of the Newer Approaches

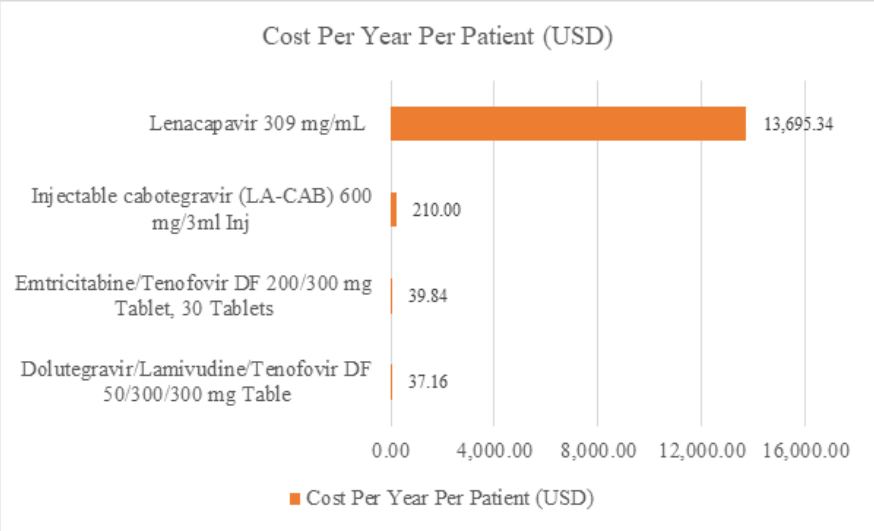
Products		FY22/23	FY 23/24	FY 24/25	FY 25/26	Notes
Total		**0**	**13,000**	**26,000**	**39,000**	
Dapivirine vaginal ring	Proportion	0%	20%	20%	20%	
	Number	-	2,600	5,200	7,800	ACP
Injectable cabotegravir (LA-CAB) 600 mg/3ml Inj	Proportion	0%	80%	80%	80%	
	Number	-	10,400	20,800	31,200	ACP

Source: Integrated Quantification Report 23/24 FY

[16]Management of Procurement and Distribution of Essential Medicines and Health Supplies by National Medical Stores, a Report by the Auditor General (December 2016)

Currently the estimated access price for cabotegravir (LA-CAB) 600 mg/3ml Inj. is USD 30 EXW per vial compared to the USD 3.32 per pack of the TDF/FTC (Oral) for PrEP[17]. An analysis was conducted to assess cost sustainability of the new molecules for PrEP. A key assumption taken was that in the first year of LA-CAB initiation 7 injections shall be required. Lenacapavir 309 mg/mL sub-cutaneous injection that showed 100% efficacy in Phase 3, PURPOSE 1 Trials in Uganda (3 sites) and South Africa (25 sites) as a 6 monthly administration was also included in the analysis. (Cost of Lenacapavir 309 mg/mL sub-cutaneous injection used was USD 6,847.67 /pack of 2 Vials[18]; it was assumed that 927mg of Lenacapavir by SC injection are required equivalent to 2 vials per dose[19]). Figure 5 below demonstrates the product cost difference for a single year of PrEP intervention for all regimen options and cost comparison to HIV 1L Treatment on TDF/3TC/DTG.

Figure 5: Price comparison between Existing TDF/FTC (Oral), TDF/3TC/DTG, and Injectable cabotegravir (LA-CAB) 600 mg/3ml Inj



The product cost of the existing regimen for PrEP is comparable to the treatment product cost for majority of PLHIV (>90%), treatment on TDF/3TC/DTG for a year being 7% cheaper. It is, however, well documented that TDF/FTC (Oral) for PrEP though highly effective when taken as prescribed, presents challenges of high loss to follow up in part due to bill burden, stigma, and discrimination some people may face when taking or storing oral PrEP pills, thus the long-acting new molecules would be key to improving PrEP adherence and persistence. The current negotiated product cost of LA-CAB for a year is USD 173 above the current treatment cost on TDF/3TC/DTG (a 465% price difference). It would cost the Ugandan program USD 51,030,000 to achieve the FY 23/24 ACP PrEP target of 243,000 on LA-CAB, representing 40% of the HIV treatment commodities procurement budget for FY23/24. The current price of LA-CAB is therefore still high. Though Lenacapavir is promising, the price also requires negotiation if the same is to benefit LMICs. According to a separate study, injectable lenacapavir could be mass produced for approximately USD 94 pppy for 1 million and USD 41 for 10 million treatment-years, if voluntary licences are in place and competition between generic suppliers substantially improves[20]. The price of long-acting injectable Cabotegravir/Rilpivirine (LA CAB/RPV) is equally high.

[17]Pooled Procurement Mechanism Reference Pricing Version Q2 2024 – April 2024

[18]https://www.drugs.com/price-guide/sunlenca

[19]https://www.uspharmacist.com/article/pioneer-hiv-capsid-inhibitor

[20]https://academic.oup.com/jac/advance-article-abstract/doi/10.1093/jac/dkae305/7748089?redirectedFrom=fulltext

For TB, a breakdown of procurements was not provided, nor could government procurements be accessed. However, Global Fund procurements are sourced through GDF as earlier mentioned and prices of order transaction for 2023 reported in PQR are listed in Table 19 above.

HCV DAAs are not currently supported by the government or donors. Patients are referred to private sector pharma distributors. One distributor of generic Sofosbuvir (400mg)/Daclatasvir (60mg), and Sofosbuvir (400 mg)/Velpatasvir (100 mg) did not have the products in stock at the time of this report and declined to quote price as quantities are only imported on order and prices are volatile due to freight. This implies that the product is not readily available for supply and lead times are highly variable depending on stock availability with the manufacturer impacting access to vital direct acting antivirals. With a second distributor of branded Sofosbuvir (400 mg)/Velpatasvir (100 mg), a pack of the FDC was priced at UGX 1,400,000 (USD 376.32). In comparison, a generic from GF PPM costs USD 58.00 before freight and insurance, a 549% difference.

6.0 CONCLUSION

1) HIV, TB, and HCV Burden

Uganda faces significant health challenges with high burdens of HIV, TB, and HCV. Epidemiology data indicates substantial numbers of patients in need of continuous treatment and care. For example, the country has substantial numbers of patients requiring HIV treatment, particularly those on first line (FL) [1.2M] and second line (SL) regimens [43k]. Cervical cancer is the leading cancer among women in the country and the most prevalent among those of reproductive age (15-44). There is limited data on the burden of HCV in the country, according to the WHO the actual prevalence of Viral Hepatitis C in Uganda is unknown, the data from the National Blood Bank indicates that the prevalence of Hepatitis C among blood donors in Uganda is approximately 1.5%.

2) National Treatment Guidelines and Essential Medicines List

Uganda's national treatment guidelines align with WHO recommendations for HIV and TB. However, the NTG for HCV issued in 2019 needs an update to be in full accordance with 2022 WHO recommendations for HCV management.

- The current NTG for HCV defers treatment for <12 years until 12 years of age in those without cirrhosis or with only compensated cirrhosis. The 2022 updated WHO guidelines lower treatment age to those between 3 to 12 years of age i.e., older children (6–11years) (all strong recommendation) and younger children (3–5 years) (conditional recommendation).
- Glecaprevir/Pibrentasvir a shorter 8-week regimen has been introduced as an alternative to the 12-week course of Sofosbuvir/Daclatasvir (most widely used) and Sofosbuvir/Velpatasvir in new WHO recommendations
- The national guideline has the following regimens for use in adolescents aged 12–17 years or weighing at least 35 kg with chronic HCV infection, use: sofosbuvir/ledipasvir for 12 weeks in genotypes 1, 4, 5 and 6, sofosbuvir/ribavirin for 12 weeks in genotype 2 and 24 weeks in genotype 3. Sofosbuvir/Ribavirin was not retained in the updated WHO recommendation. Ribavirin requires hematological monitoring and is teratogenic hence its replacement.

There are gaps where essential medicines for management of HCV are missing from the Essential Medicines List 2023. For TB, Pretomanid 200 mg Tablet that is an import molecule in the BPaLM regimen, a newly recommended WHO combination for people with MDR/RR-TB is also missing on the EMHSL 2023.

The country is yet to adopt other newly emerging molecules i.e., long-acting injectable Cabotegravir/Rilpivirine (LA CAB/RPV) and Lenacapavir 309 mg/mL sub-cutaneous injection that are USFDA approved (high-income country) but are currently not recommended by the WHO.

3) Funding and Procurement

The national budget for HIV and TB medicines heavily relies on international donors, however there are no notable funding gaps for commodities in FY23/24. For FY 23/24, GOU contributes $52,631,567, which is 41% of the total funding towards the HIV commodities budget, TGFATM contributes $51,430,677, accounting for 40% and PEPFAR contributes $23,731,851, representing 19% of the total funds.

Procurement mechanisms in government often lack transparency for external stakeholders i.e., civil society, advocacy groups, regarding pharmaceutical expenditures within the health sector budget which is critical to allocate resources more effectively. None of the recent Office of the Auditor General (OAG) Reports have reported on price benchmarks or value for money. The 2016 OAG report on NMS indicated that the local manufacturer's prices were dictated by the MoU that was signed between MoH on behalf of GoU and the manufacturer with provision for negotiations. It also provided for procurement of all ARVs from the local manufacturer by government. The 2016 OAG report however noted that (5) out of the eight (8) selected donor sourced drugs were on average cheaper than those of the local supplier prices. The percentage average difference for three (3) out of the five (5) drugs was found to be more than 25%. i.e., Lamivudine/Zidovudine 150/300 mg Tablet, and Lamivudine/Tenofovir DF 300/300 mg Tablet, were 13% and 28% higher than the donor price respectively.

99% of the volume delivered by packs in 2023 were from generic sources. Dolutegravir/ Lamivudine/Tenofovir DF 50/300/300 mg Tablet makes up 75% of the delivered volume by packs, Abacavir/Lamivudine 120/60 mg [UG] Tablet, 30 Tablets the main anchor for pediatric dosage forms makes up 7% of the delivered volume, Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets for Pre-Exposure Prophylaxis makes up 5% of the delivered volume, Dolutegravir 10 mg Tablet, 30 Tablets for pediatrics makes up 3% of delivered volume, Dolutegravir 50 mg Tablet, 30 Tablets and Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets both make up 2% of the delivered volume. Third liners where some branded products are sourced make up <0.5% of the delivered volume.

4) Supply Chain Challenges

There are significant challenges in the supply chain for HCV treatment products. HCV DAAs are not currently supported by the government or donors. Patients are referred to private sector pharma distributors. One distributor of generic Sofosbuvir (400mg)/Daclatasvir (60mg), and Sofosbuvir (400 mg)/Velpatasvir (100 mg) did not have the products in stock at the time of this report and declined to quote price as quantities are only imported on order and prices are volatile due to freight. This implies that the product is not readily available for supply and lead times are highly variable depending on stock availability with the manufacturer impacting access to vital direct acting antivirals. The only MA holder for Sofosbuvir (400 mg)/Velpatasvir (100 mg) for management of HCV on the national drug register is from a proprietary brand that is quite costly.

5) Commodity Prices

There is a need for increased stakeholder engagement to understand and address prices

for new and emerging PrEP commodities and branded HCV commodities. Ensuring equitable access to long acting injectable antiretrovirals and HCV DAAs remains a critical challenge. The product cost of the existing regimen for PrEP is comparable to the treatment product cost for majority of PLHIV (>90%), TDF/3TC/DTG for a year being 7% cheaper. It is however, well documented that TDF/FTC (Oral) for PrEP has a high loss to follow up in part due to bill burden and stigma, thus the long-acting new molecules would be key to improving adherence. The current negotiated product cost of LA-CAB for a year is USD 173 above the current treatment cost on TDF/3TC/DTG (a 465% price difference). It would cost the Ugandan program USD 51,030,000 to achieve the FY 23/24 ACP PrEP target of 243,000 on LA-CAB, representing 40% of the HIV treatment commodities procurement budget for FY23/24. The current price of LA-CAB is therefore still high. Though Lenacapavir is promising, the price also requires negotiation if the same is to benefit LMICs. The price of long-acting injectable Cabotegravir/Rilpivirine (LA CAB/RPV) is in the same region.

The only local distributor with stock for HCV DAA that had branded Sofosbuvir (400 mg)/Velpatasvir (100 mg), a pack of the FDC was priced at UGX 1,400,000 (USD 376.32). In comparison, a generic from GF PPM costs USD 58.00[21] before freight and insurance, a 549% difference.

[21]Pooled Procurement Mechanism Reference Pricing: Strategic medicines used in HIV programs Version Q2 2024 – April 2024

7.0 RECOMMENDATIONS

1) Enhance Funding Mechanisms

The government should increase its contribution to the health commodity budget, particularly for HIV, TB, and HCV treatments, to reduce dependency on international donors. Develop sustainable funding strategies to cover gaps as donor priority pivots to Climate Change and other global health challenges in light of increasing non communicable disease burden.

2) HCV Direct Acting Antivirals (DAAs) Access and Supply Chain Challenges

Regular review and update of the NTG for HCV and the national essential medicines list to include up to date WHO recommendations for HCV management. For instance, adding newer HCV treatments that are currently missing and lowering treatment age to include 3–12-year-olds. Including all DAAs in the NTG in the EMHSLU.

Registration of NDA unregistered DAAs is a critical step towards making the medicines available for use in clinical settings i.e., 1) Sofosbuvir/daclatasvir FDC (400 mg/60 mg) from Cipla 2) Sofosbuvir/velpatasvir FDC (400 mg/100 mg) from Mylan 3) Sofosbuvir/ledipasvir FDC (400 mg/90 mg) from Mylan. There is need to engage and support manufacturers and LTRs to apply for registration of their products by the national regulatory authority. The LTRs for molecules should be supported for accelerated registration since products are WHO-prequalified.

There is need for a concerted effort among all stakeholders to influence donor and national procurement decisions towards sourcing of DAAs, especially pan-genotypic DAAs that eliminate the need for genotyping for adults in treatment to make the medication available to the most impacted vulnerable poor that access healthcare through public health facilities.

3)Community and procurement agencies dialogue with MoH, and advocate with govt to ensure inclusion of pretomanid into EMHSLU

4) Yet to be adopted newly emerging molecules i.e., long-acting injectable Cabotegravir/Rilpivirine (LA CAB/ RPV) and Lenacapavir 309 mg/mL sub-cutaneous injection that are not yet WHO recommended

WHO influences the introduction of new medical innovations in low- and middle-income countries through its clinical guidelines, prequalification process and Model List of Essential Medicines. Prequalification by WHO is often a prerequisite for donors to use their funds to purchase a particular medicine. Although primarily intended to assure the quality of medical products

procured by United Nations agencies, WHO's list of prequalified medicines has, over time, influenced National Treatment Guidelines, procurement decisions by donors and national governments. There is therefore a need to fast track WHO recommendations and prequalification of these new treatment options.

5) Price reductions on long-acting injectable antiretroviral drugs

With the introduction of new regimens like Lenacapavir, Cabotegravir (LA-CAB), and Dapivirine, managing costs effectively becomes crucial to sustaining programmatic interventions. The current high prices of these newer drugs necessitate strategic interventions to ensure broader access and cost-effectiveness.

Price Reduction Strategies:

1. Generic Competition

- Stakeholders need to urge Gilead, the manufacturer of Lenacapavir to allow generic production of the drug to all low- and middle-income countries by negotiating voluntary licensing agreements through the Medicines Patent Pool (MPP).
- Promote Generic Alternatives: Increase the use of generic alternatives where available. Generics are typically significantly cheaper than branded drugs. Ensure that regulatory pathways are streamlined to facilitate the entry of generics into the market.

2. Negotiation with Manufacturers

- Bulk Purchasing Agreements: Engage in bulk purchasing agreements with manufacturers to leverage economies of scale. This approach can help reduce the unit cost of drugs like LA-CAB and Lenacapavir.
- Tiered Pricing Models: Advocate for tiered pricing models where lower prices are offered to low- and middle-income countries (LMICs). This model has been effective in reducing costs for various essential medicines globally.

3. Pooled Procurement Mechanisms

- Expand Pooled Procurement: Utilize existing pooled procurement mechanisms such as those provided by the Global Fund and PEPFAR to negotiate better prices. These mechanisms have a track record of lowering prices through consolidated purchasing power.
- Regional Collaboration: Collaborate with other countries in the region to form a larger procurement pool. This collective bargaining power can drive down prices further.

4. Local Manufacturing

- Support Local Production: Encourage and support local production of ARVs and PrEP drugs. Local manufacturing can reduce dependency on international suppliers, lower transportation costs, and stabilize prices.
- Technology Transfer Agreements: Facilitate technology transfer agreements with international pharmaceutical companies to enhance local manufacturing capabilities and ensure quality production standards.

5. Policy and Regulatory Interventions

- Transparent Pricing Mechanisms: Establish transparent pricing mechanisms and guidelines for procurement to ensure value for money. This includes regular audits and public reporting of drug prices, especially for government procurements.

6. Donor Engagement

- Sustained Donor Support: Advocate

for sustained support from international donors for the procurement of high-cost drugs. Donor funding can help bridge the gap until prices are negotiated down.
- Co-Financing Models: Develop co-financing models where both the government and donors contribute to the cost of high-priced medications, reducing the financial burden on any single entity.

7. Innovative Financing Mechanisms

- Health Bonds and Subsidies: Explore the use of health bonds or subsidies to finance the procurement of expensive drugs. These mechanisms can provide the necessary upfront capital while spreading the cost over time.
- Global Health Initiatives: Leverage global health initiatives and funds aimed at reducing the cost of essential medicines for LMICs.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