





# 2021 Annual ARV Buyer Seller Summit

Master Slide Deck







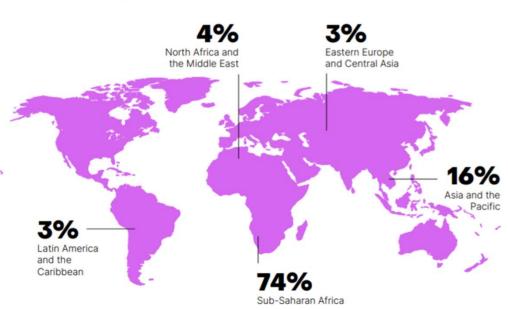
## Annual ARV Buyer Seller Summit Table of Contents

ΤΟΡΙϹ	SPEAKERS/MODERATORS							
Welcome Remarks	Mr. Cathal Meere, Pharma Sourcing Manager, The Global Fund Ms. Khadija Jamaloodien, Director of Affordable Medicines, South Africa National Department of Health Dr. Christine Malati, Pharmaceutical Adviser, Office of HIV/AIDS, USAID	3						
		14						
18 Month Consolidated Forecast	Mr. Rajeev Batohi, South Africa Lead, Africa Resource Centre	29						
Individual Highlights for Each Procurement Channel with	<b>Ms. Tsion Tsegaye Gizaw,</b> <i>Procurement Contract Management Expert, Ethiopia Pharmaceuticals Supply Agency</i>	53						
opportunity for Q&A	Mr. Zafar Yuldashev, Procurement Specialist, United Nations Development Programme Moderated by Mr. Daniel Kiesa, Senior Adviser for Market Intelligence, USAID	62						
Individual Highlights for Each	Mr. Dessalegn Tesfaye, Senior Supply Chain Advisor, USAID/Rwanda	74						
Procurement Channel with opportunity for Q&A	Ms. Suzan NakawUnde, Health Commodities Programme Management Specialist, USAID/Uganda Moderated by Dr. Messai Belayneh, Pharmaceutical and Supply Chain Advisor, USAID	83						
PEPFAR Priorities	Dr. Katy Godfrey, Senior HIV Care and Treatment Technical Adviser, S/GAC	91						
	Dr. Hilary Wolf, Senior Pediatric Technical Adviser, S/GAC	107						
	Dr. Sara Klucking, HIV Prevention Lead, S/GAC	114						
	Dr. Kanjinga Kakanda, Senior TB/HIV Technical Advisor, S/GAC Moderated by Dr. Christine Malati, Pharmaceutical Adviser, USAID	119						
Individual Highlights for Each Procurement Channel with	Mr. Alan Pringle, Global Supply Chain Director, Global Health Supply Chain – Procurement & Supply Management	126						
opportunity for Question and	Ms. Khadija Jamaloodien, Director of Affordable Medicines, Republic of South Africa	133						
Answer	Ms. Uranchimeg Badarch, Specialist, Strategic Sourcing Pharmaceuticals, The Global Fund	143						
	Mr. Jordi Balleste, Unit Chief, Strategic Fund Procurement, Procurement and Supply Management, Pan	153						
	American Health Organization Moderated by Mr. Daniel Kiesa, Senior Adviser for Market Intelligence, USAID							
GS1 Rollout	Ms. Lindabeth Doby, Senior Management Information Systems Advisor, USAID	165						
	<b>Mr. Mathieu Courtois,</b> Manager, Data, Analytics, Processes and Tools Team/Head of Wambo, The Global Fund	172						
	Mr. Umesh K, Senior Vice President for Global Antivirals, Aurobindo Pharma Limited	181						
	<b>Ms. Rachel Smith,</b> Global Standards Technical Specialist, Global Health Supply Chain – Procurement & Supply Management	188						

5		TH GL( FU	E OB ND	BAL	•	•	8 2 8 8							•	•	 •	•	•	•	•	•	•	•	•	•
A	• •	nı		a	•	Â	, R		•	B	Ve	er		5	el	91	5	5		m		ni	•	•	•
00								X	•	•		•			•			÷	•			•		•	•
•••	•	•	•	•	•	•	•						•							•	•	•	•		•
•••	•	•	:	•	•	•	•					•					•	•	•	•	•	•	•	•	•

# **Investing for Impact**

- The Global Fund is one of the world's largest funders of global health.
- We have disbursed more than US\$50 billion since 2002 to respond to HIV, TB and malaria and for programs to strengthen systems for health across more than 155 countries, including regional grants.



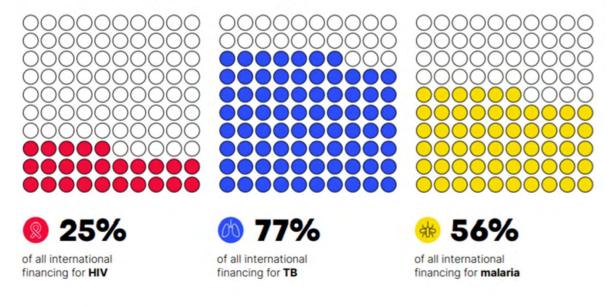
Global Fund investments by region

In 2019-2021 as of June 2021

**今 THE GLOBAL FUND** 

# **Investing for Impact**

### International grants provided by the Global Fund in 2020

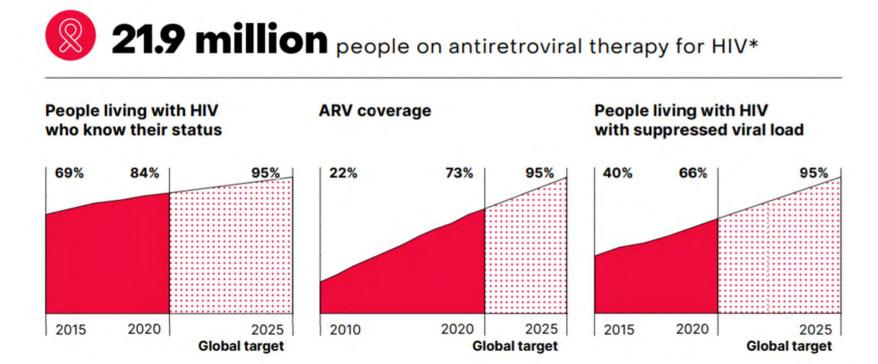


<sup>6</sup> The Global Fund measures overall funding in US dollars but pledges and contributions are made in multiple currencies.

S THE GLOBAL FUND

# **HIV: State of the Fight in the Time of COVID-19**

Key HIV results for 2020 in countries where we invest



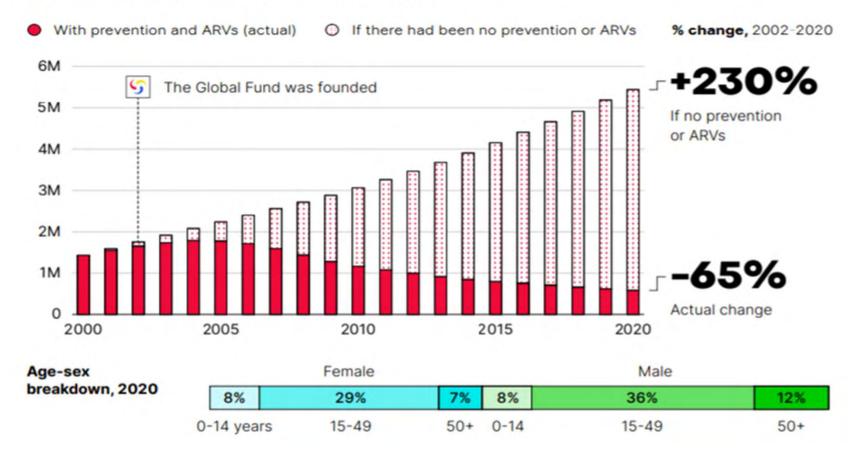
#### S THE GLOBAL FUND

\*Programmatic results achieved during 2020 by countries and regions where the Global Fund invests. Progress graphs are based on latest published data from WHO (2020 release for TB and malaria) and UNAIDS (2021 release). Malaria coverage calculated based on 38 African countries for which data is available from WHO / Malaria Atlas Project estimates.

4

## **Trends in AIDS-related deaths**

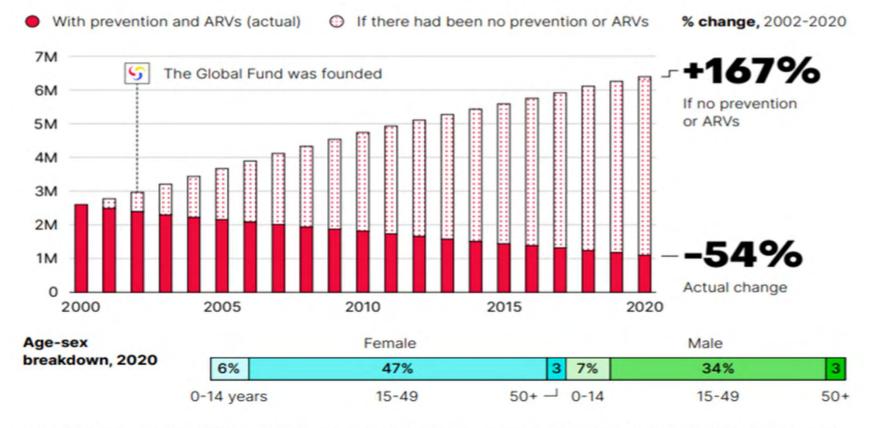
In countries where the Global Fund invests



**今 THE GLOBAL FUND** 

## **Trends in new HIV infections**

### In countries where the Global Fund invests

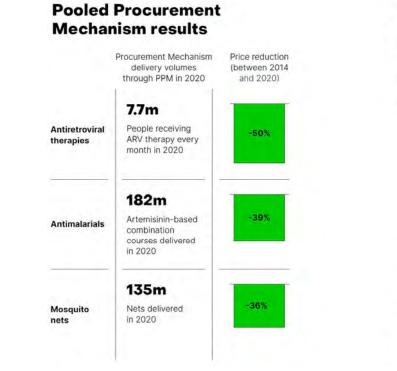


HIV burden estimates from UNAIDS, 2021 release. Estimation of "no prevention or ARVs" trends from Goals, AEM and AIM models.

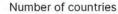
#### S THE GLOBAL FUND

# Investing for Impact

# **Pooled Procurement Mechanism Savings**



### Financial management systems meeting defined standards





Defined standards are measured as at least 80% of agreed actions for improvement of financial systems implemented. Countries where the use of Public Financial Management Systems or Donor Harmonized Systems are not feasible, therefore the Global Fund supports grant implementers to strengthen their linancial management systems for effective and efficient management of grants/programs. Agreed actions's related to strengthen their linancial management systems for offective and efficient management of grants/programs. Agreed actions's related to strengthen the poople, processes and information systems of financial management systems. Financial management systems related to a grade actions to strengthen the poople, processes and information systems of financial management systems. Financial management systems method to of multiple RSDH key performance indicators.

#### S THE GLOBAL FUND

# Fighting COVID-19

# Time for another global push to save lives

#### How countries are using the COVID-19 Response Mechanism

As of August 2021

As of August 2021, we had approved US\$4 billion to support countries to respond the pandemic with critical tests, treatments and medical supplies, protect front-line health workers, adapt lifesaving HIV, TB and malaria programs, and reinforce fragile systems for health







#### **Reinforcing national COVID-19 response**

Including purchasing critical tests, treatments, oxygen and medical supplies; protecting front-line health workers with training and PPE like gloves and masks; and supporting control and containment interventions, including test, trace and treat/isolate.

#### Mitigating COVID-19 impact on HIV, TB and malaria programs

Including by delivering medicines, mosquito nets and critical supplies door to door, protecting community health workers and providing support and prevention services via digital platforms.

#### Making urgent improvements to health and community systems to help fight COVID-19, HIV, TB and malaria Including by reinforcing supply chains, laboratory

networks and community-led response systems.

**今 THE GLOBAL FUND** 

# **Global Fund Results Report 2021**

Feature Film: We Can't Go Backwards



S THE GLOBAL FUND

Just as 20 years ago, when the Global Fund partnership galvanized the world to fight the world's leading infectious diseases, it is time for another global push to save lives. We must protect the gains made against HIV, TB and malaria.

Peter Sands Executive Director of the Global Fund



# Thank you

**S**THE GLOBAL FUND

The Global Fund to Fight AIDS, Tuberculosis and Malaria

+41 58 791 1700 theglobalfund.org





# Welcome to the ARV Summit!

# Christine Y. Malati, PharmD 13 to 14 October 2021 2021 Annual ARV Buyer Seller Summit

18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

**GOAL** Equip ARV manufacturers with an understanding of PEPFAR priorities to inform research, development, and manufacturing plans.

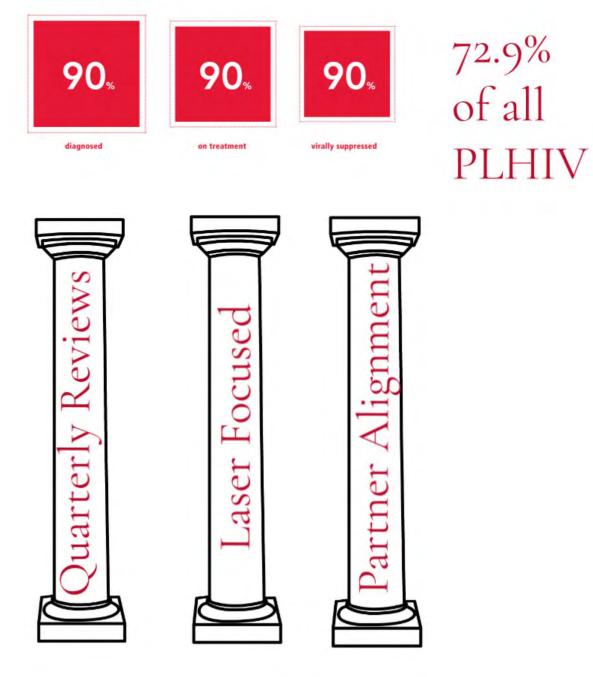
OBJECTIVES

1. Celebrate the accomplishments of the past 18 years of PEPFAR. 2. Explain the impact of treatment optimization on product forecast and viral load suppression. 3. Articulate strategies for ensuring a client centered supply chain with private sector engagement.









THE TREATMENT TARGET

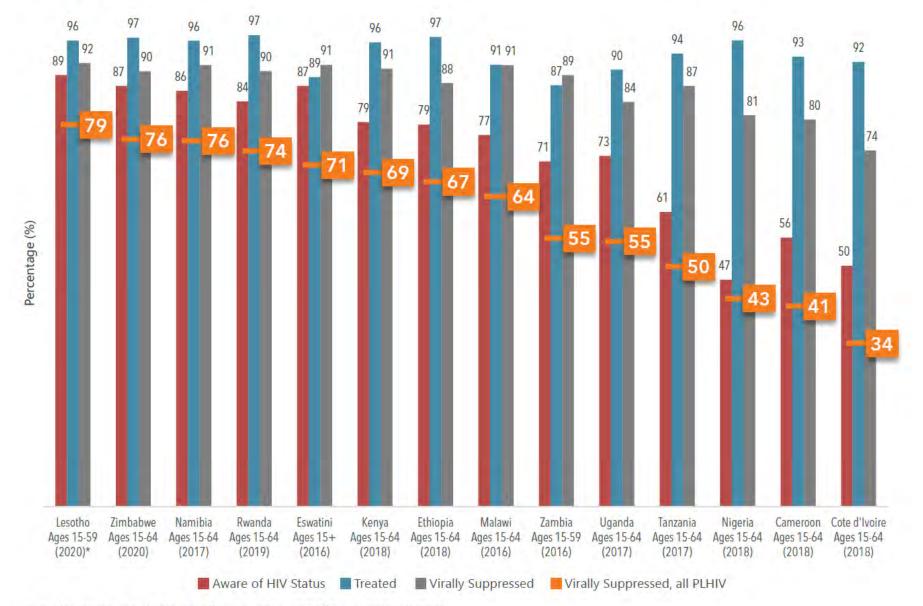
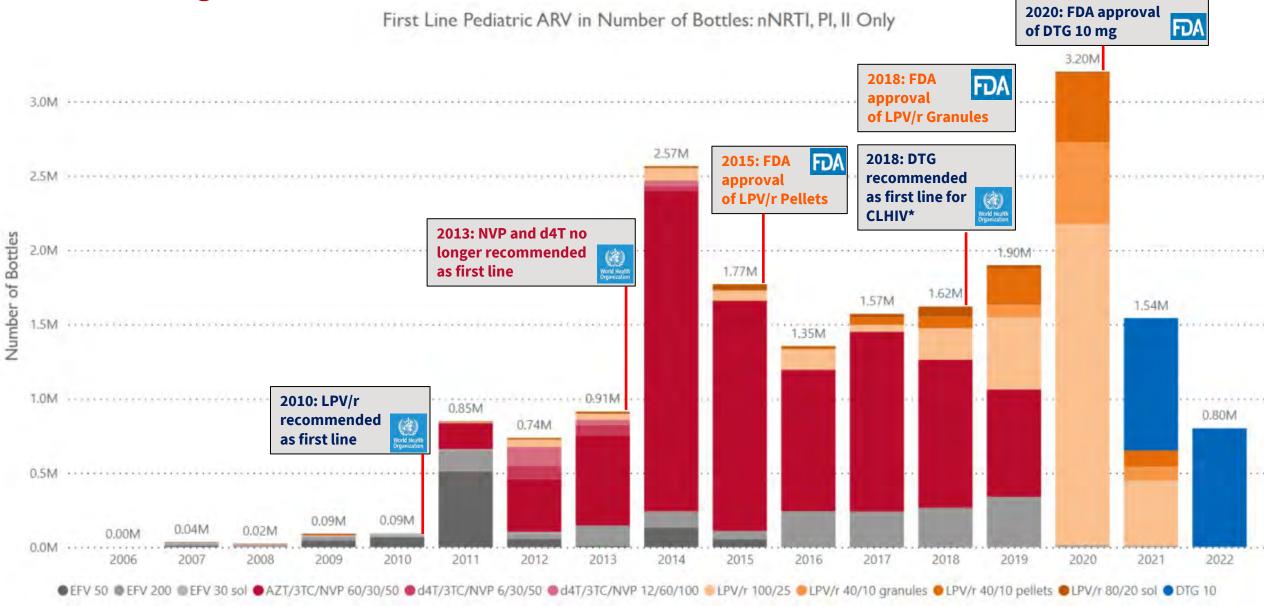


Figure 1. PEPFAR-funded PHIAs – Countries Showing Achievements toward the Global HIV SDG 90/90/90 Goals

\*Lesotho results are viral load-adjusted; other countries are ARV-adjusted

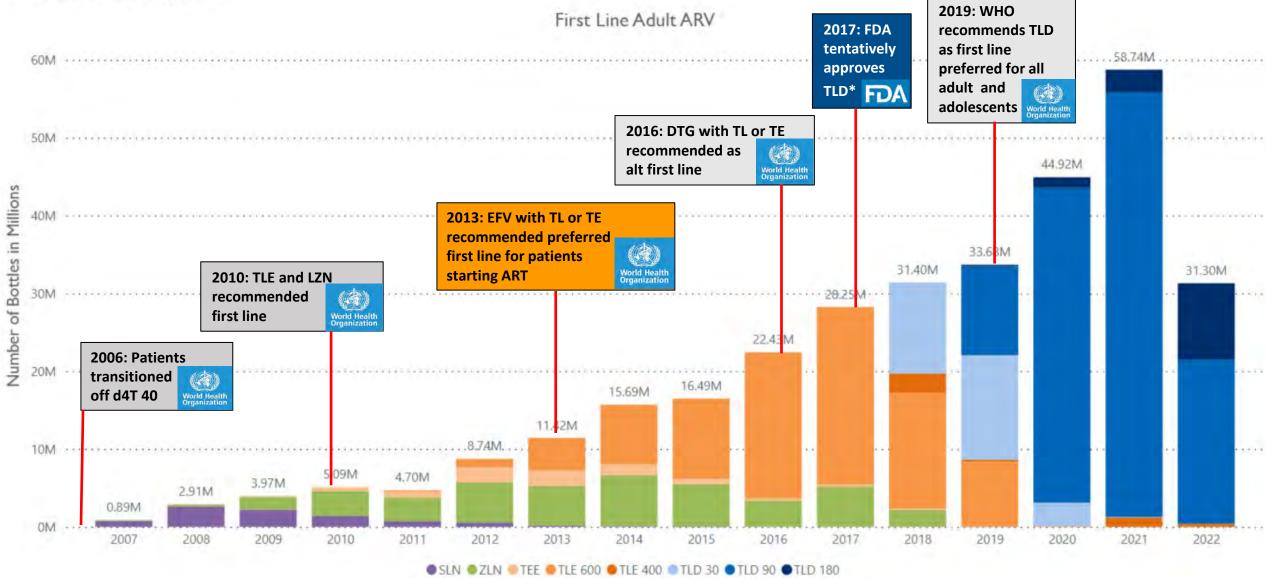
# Pace and Magnitude of Paediatric ARV Transitions



Source: GHSC-PSM. Data current as of October 12, 2021.

# Pace and Magnitude of Adult ARV Transitions

All TLD shown in TLD 30 equivalents



Source: GHSC-PSM. Data current as of October 12, 2021.

# **ARV Optimization, FY21 Q2** Adult ARVs by regimen, percent of total

Malawi		99%	D						
South Sudan		98%							
Lesotho		95%			4%				
/lozambique		94%			4%				
Haiti		94%			4%				
DRC		92%			8%				
Tanzania		91%			<b>5%</b> 4%				
Nigeria		90%			9%				
Namibia		82%			17%				
Zambia		79%			16% 4%				
Botswana		79%			8% 13%				
Ethiopia	76% 16% 7%								
Uganda		76%		3% 4					
Cote d'Ivoire									
Eswatini	71% 15%								
Kenya		71%		6%	23%				
WH		70%			2% 6%				
Rwanda		8%		19%	13%				
Cameroon	67			13%	8% 11%				
Burundi	66				20% 7%				
Zimbabwe	64%			24%	11%				
WAR	60%		0.10/	31%	3% 5%				
South Africa	46%	100/	24%	20%					
DR	36%	18%	12%	500/	33%				
Asia Region 17% Angola 9%	25%	5% 81%	6	53%	10%				
0%	20%	40%	60%	809					

Show Data by:

Regimen View All Regimens

Regimen Type All

Age Adult

OU All

Indicator SC\_ARVDISP

Agency All

Partner All

SNU All

PSNU All

30-Count Equivalents 30-count equivalents

OU

Period FY21 Q2

i

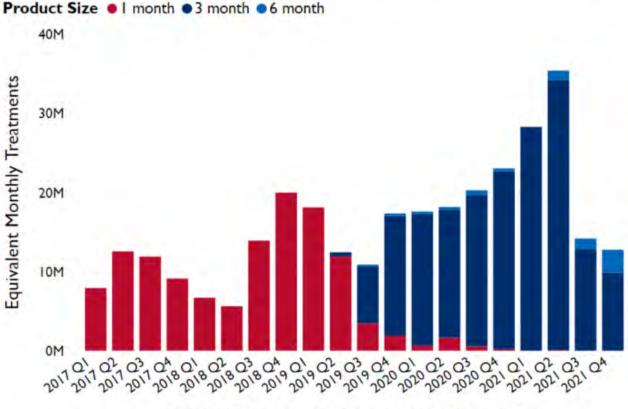
SC\_ARVDISP, 30-count equivalents

TLD NVP

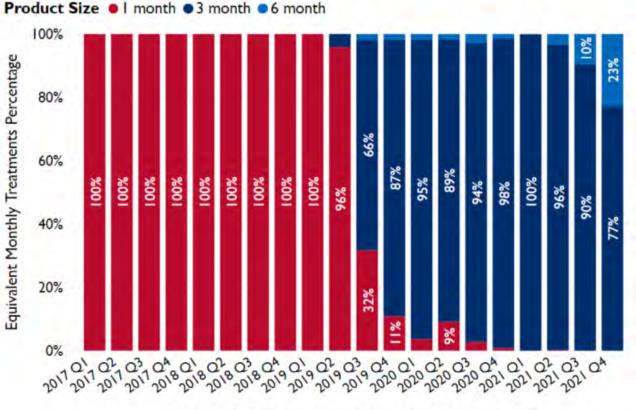
TLE 400 Other

TLE 600/TEE

## Products Procured by PSM in Equivalent Monthly Treatments Categorized by 1, 3, + 6 Month Product Size



Calendar Year, Quarter by Estimated/Actual Delivery Date



Calendar Year, Quarter by Estimated/Actual Delivery Date

#### Adult ARVs Included

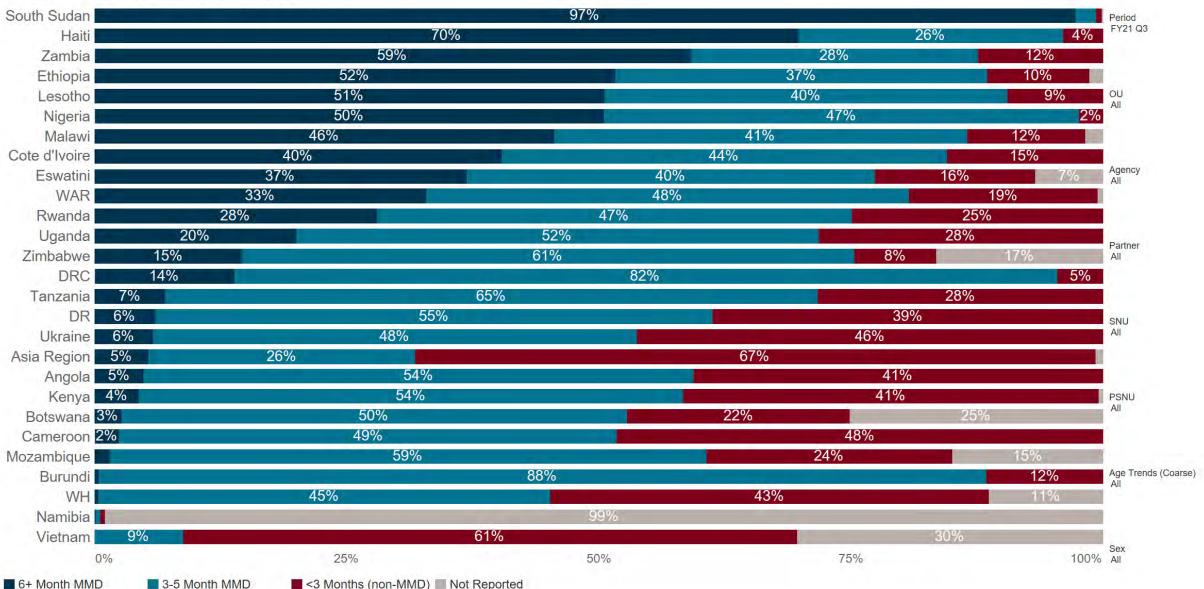
TAF-ED: Dolutegravir/Emitricitabine/Tenofovir AF 50/200/25 mg Tablet, 30 Tablets, Dolutegravir/Emitricitabine/Tenofovir AF 50/200/25 mg Tablet, 90 Tablets

TLD: Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 100 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 28 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets, Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets

TLE: Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 30 Tablets, Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 90 Tablets, Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablet, 100 Tablets, Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablet, 30 Tablets, Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablet, 30 Tablets, Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablets, 90 Tablets, Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablets, E

LZN: Nevirapine/Lamivudine/Zidovudine 200/150/300 mg Tablet, 30 Tablets, Nevirapine/Lamivudine/Zidovudine 200/150/300 mg Tablet, 60 Tablets

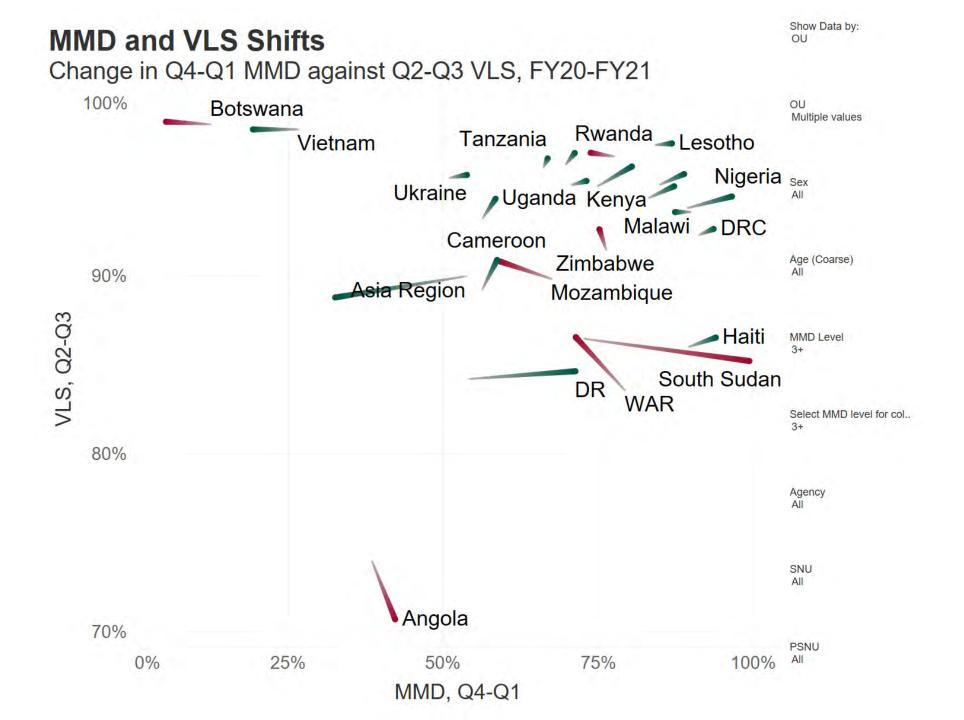
# MMD Levels, FY21 Q3 TX\_CURR by MMD Duration



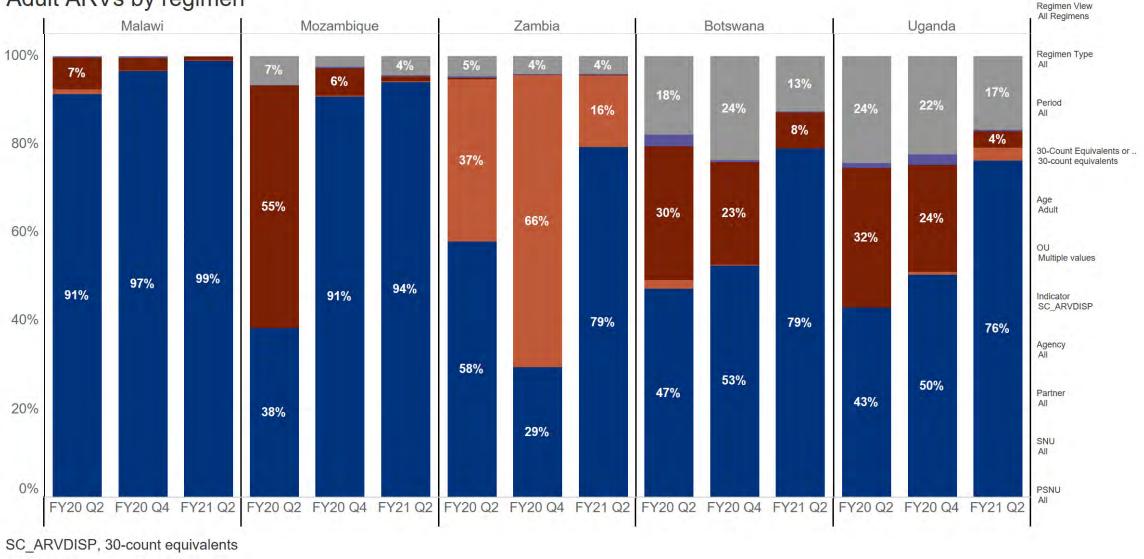
6+ Month MMD

<3 Months (non-MMD) Not Reported</p>

Show Data by: OU



## ARV Optimization Trends Adult ARVs by regimen



Other NVP TLE 600/TEE TLE 400

TLD

Show Data by: OU



1. DELIVER inclusive people-centered HIV Px and Tx Services

2. SUPPORT resilient and capacitated partner country health and community systems

3. PARTNER for greater impact, burden sharing and sustainability

# 1. Local Procurement Service Agents



Rwanda Medical Supply



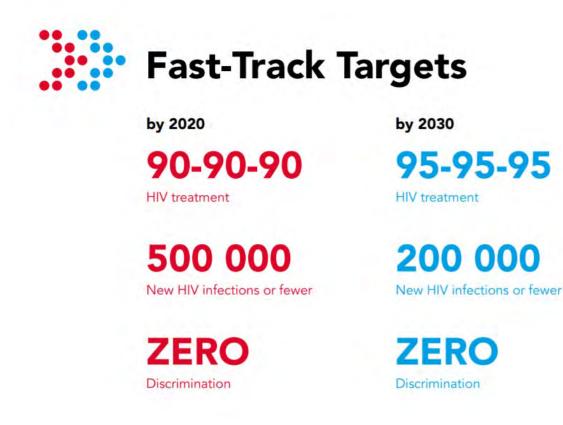
Joint Medical Stores

Medical Access Uganda Limited

2. Vendor Managed Solutions
3. Long acting formulations
for prevention and
treatment



# All of these interventions will enable us to achieve 95 95 95 by 2030!



# Thank you!

# **2021 ANNUAL ARV BUYER SELLER SUMMIT**

# **18 MONTH CONSOLIDATED FORECAST**

Oct 2021









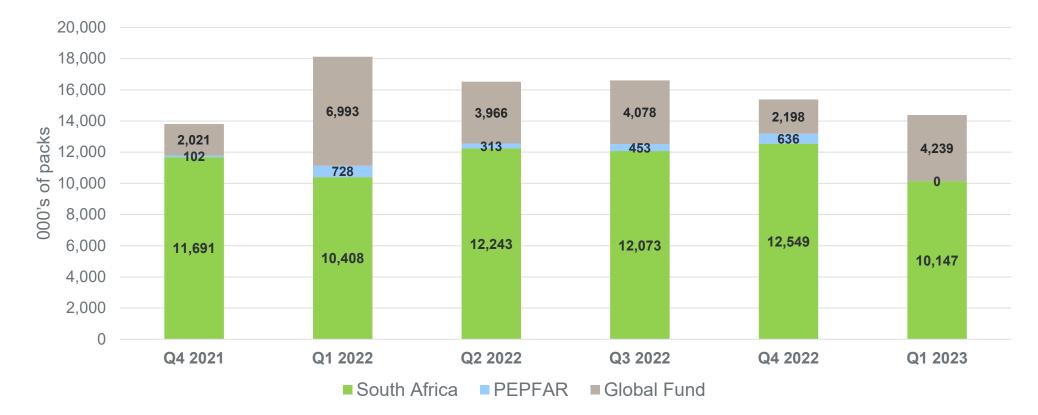
**Republic of South Africa** 

# CAVEATS AND LIMITATIONS TO THE CURRENT VERSION OF THE VISIBILITY DATA

- Conservative estimates based on currently confirmed orders and firm demand
- Prepared based on **data currently available** to The Global Fund, PEPFAR, and South Africa
  - TGF forecast for Q1 2023 is a conservative estimate of current demand visibility; this is to account for any influence of the Global Fund Grant Cycle (i.e. final year of grant) versus real demand; additional volumes may materialize
  - Includes data from UNDP
- Preliminary estimates for discussion and planning not final purchase commitments
  - Some country submissions used the July 2021 submission instead of the Oct 2021 submission; TBD volumes were not included
- May not yet fully capture lead times between order placement at manufacturer and in-country delivery
- Tenth joint consolidated procurement forecast. Next scheduled release is May 2022.

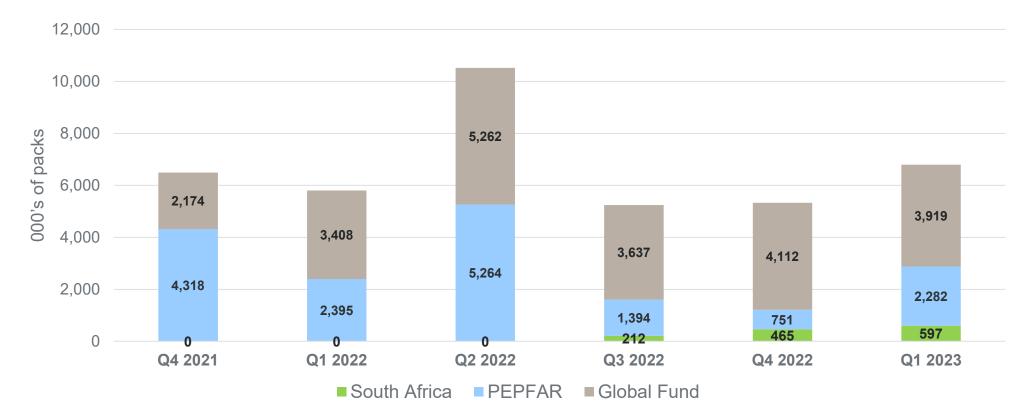


# TLD 28-30 TABLETS; SOUTH AFRICA IS THE MAIN MARKET





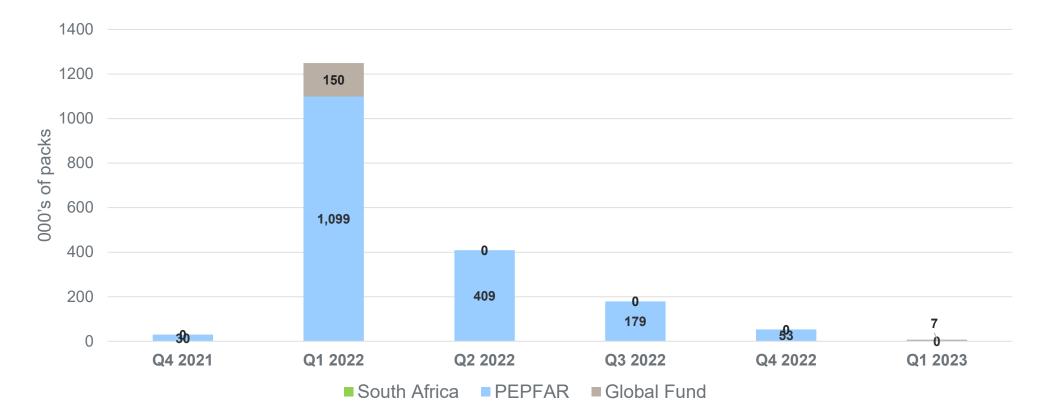
## TLD 84-90 TABLETS; HIGH DEMAND FOR Q2 2022





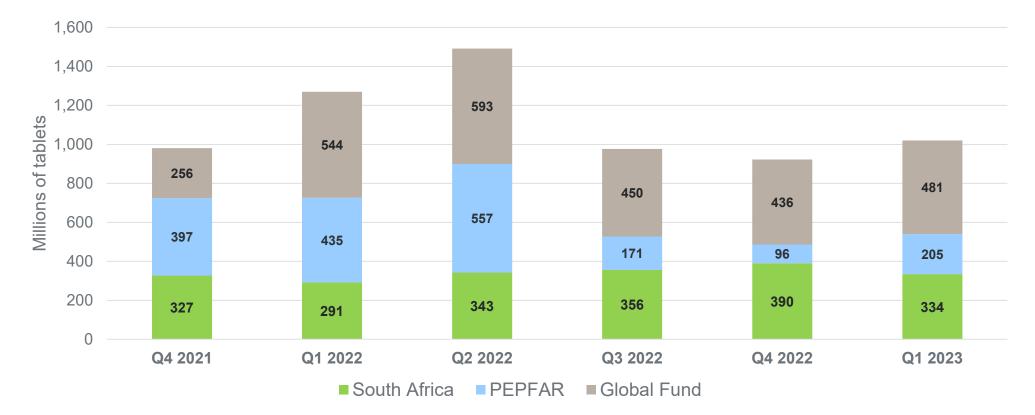
Source: Submissions from GHSC-PSM, Global Fund, South Africa, Ethiopia, Uganda Notes: SA volumes subject to 2022 tender award outcome

## TLD 180 TABLETS; PEPFAR DRIVING DEMAND





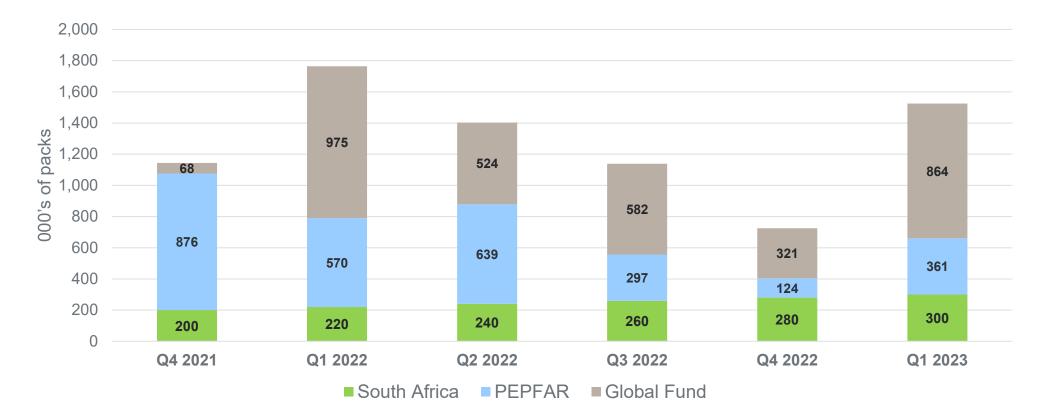
## TLD TABLETS (ALL PACK SIZES)





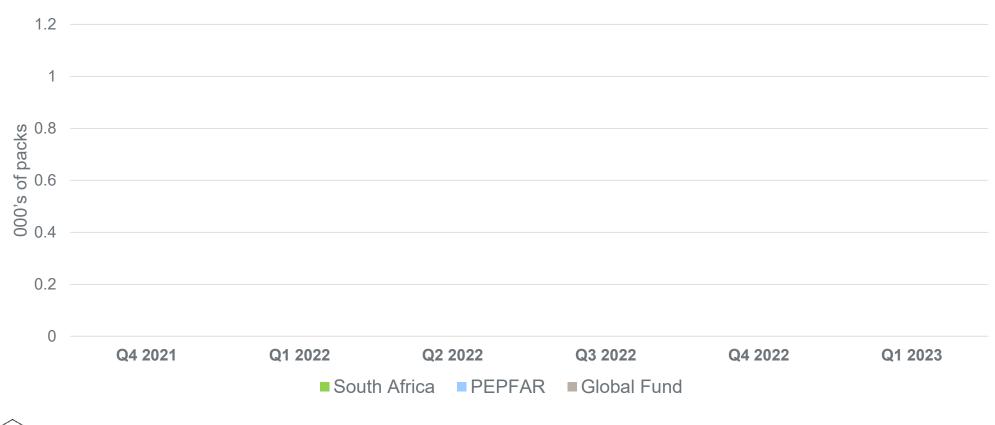
Source: Submissions from GHSC-PSM, Global Fund, South Africa, Ethiopia, Uganda Notes: Note the switch from packs to millions of tablets for this graph.

# DTG 50 MG, 30 TABLETS; CYCLICAL DEMAND WITH Q1 PEAKS



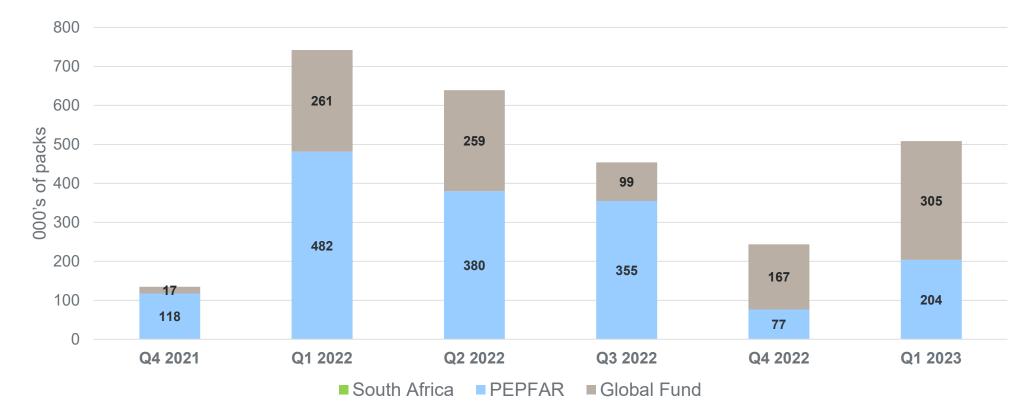


## DTG 50 MG, 90 TABLETS; NO DEMAND INDICATED





### DTG 10 MG, 90 SCORED, DISPERSIBLE TABLETS

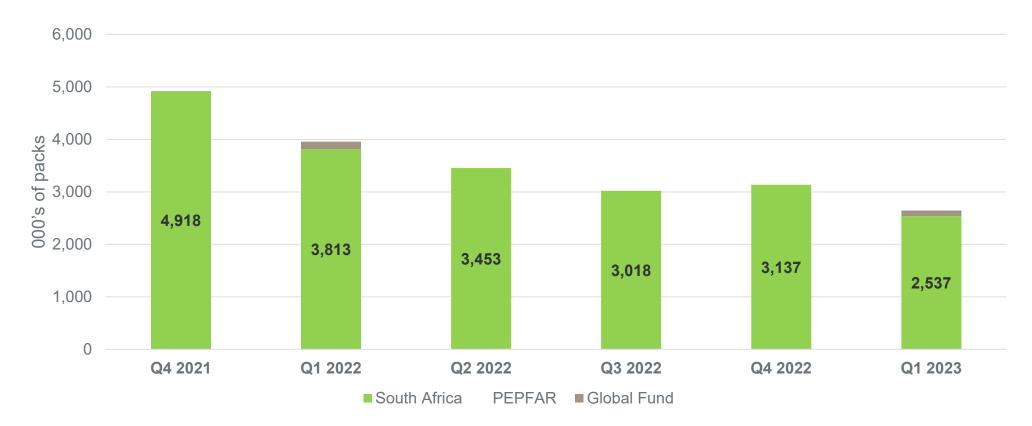




Source: Submissions from GHSC-PSM, Global Fund, South Africa, Ethiopia, Uganda

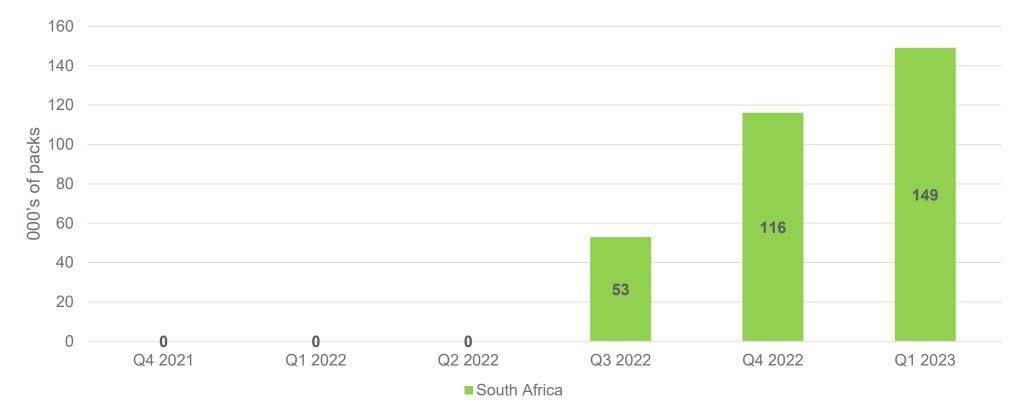
Notes:TGF forecast for DTG10 is based on an anticipated shift in demand from paediatric LPV/r (pellets, granules, and tablets) - which is not yet in grant planning documents

## TEE/TLE 600 MG, 28 TABLETS; SOUTH AFRICA IS THE MAIN MARKET



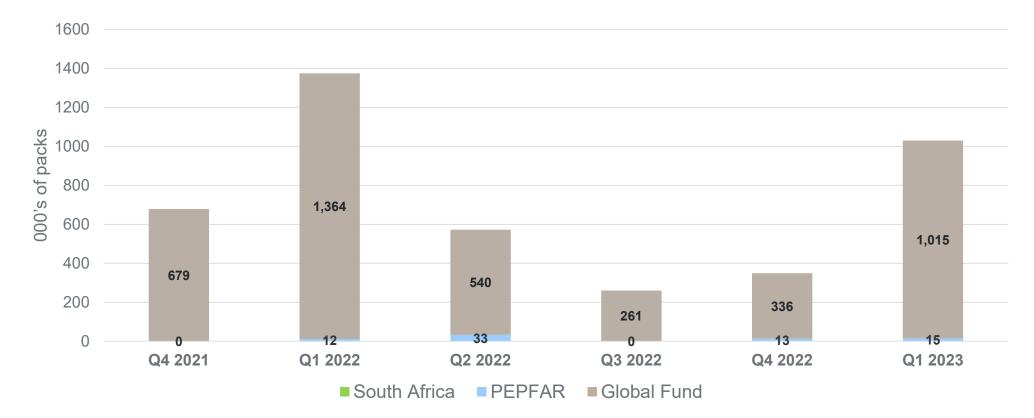


## TEE 600 MG, 84-90 TABLETS; SOME DEMAND EXPECTED IN SOUTH AFRICA IN THE NEW TENDER



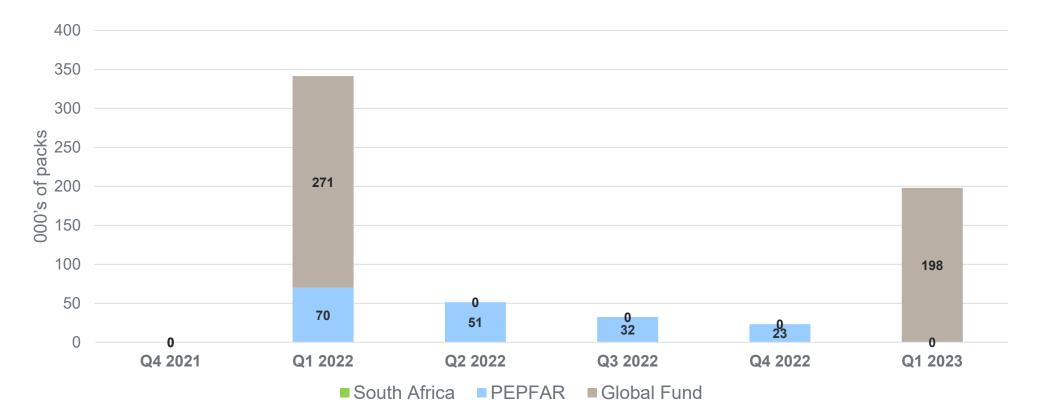


## TLE 400 MG, 30 TABLETS; GLOBAL FUND IS THE MAIN DRIVER



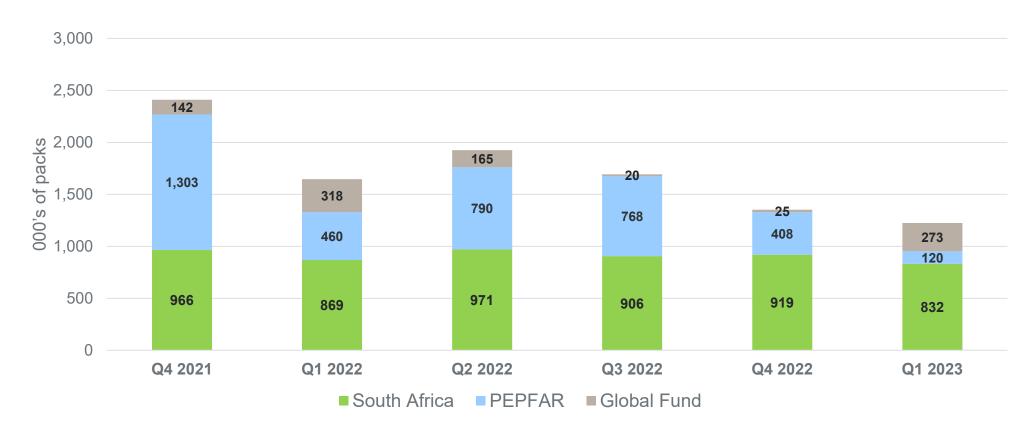


## TLE 400 MG, 90 TABLETS; LARGE CYCLICAL Q1 DEMAND INDICATED



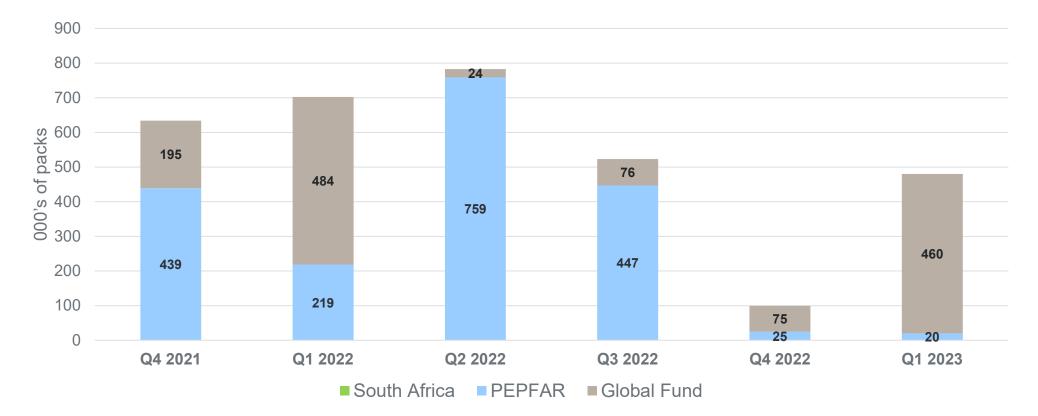


### TDF/FTC 300/200 MG, 30 TABLETS



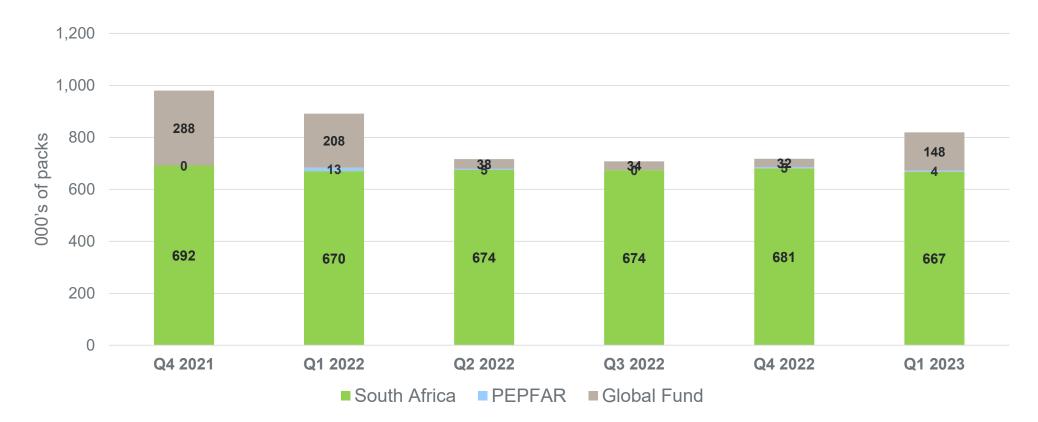


## TDF/3TC 300/300 MG, 30 TABLETS; DEMAND DROPS OFF LATER IN PLAN



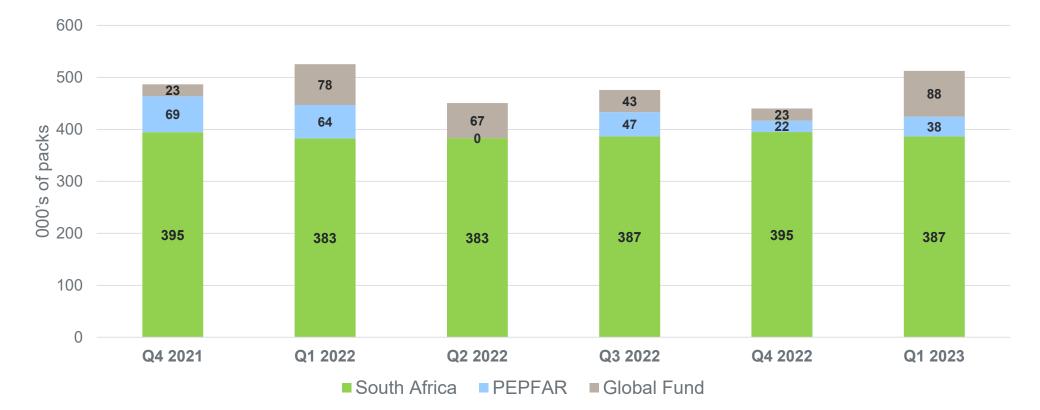


### LPV/r 200/50 MG, 112-120 TABLETS





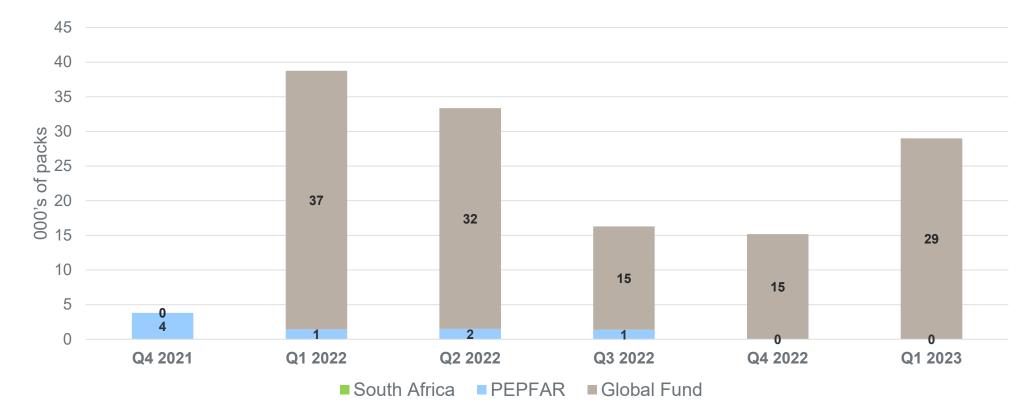
### LPV/r 100/25 MG, 56-60 TABLETS





Source: Submissions from PEPFAR, Global Fund, South Africa, Ethiopia, Uganda Notes:

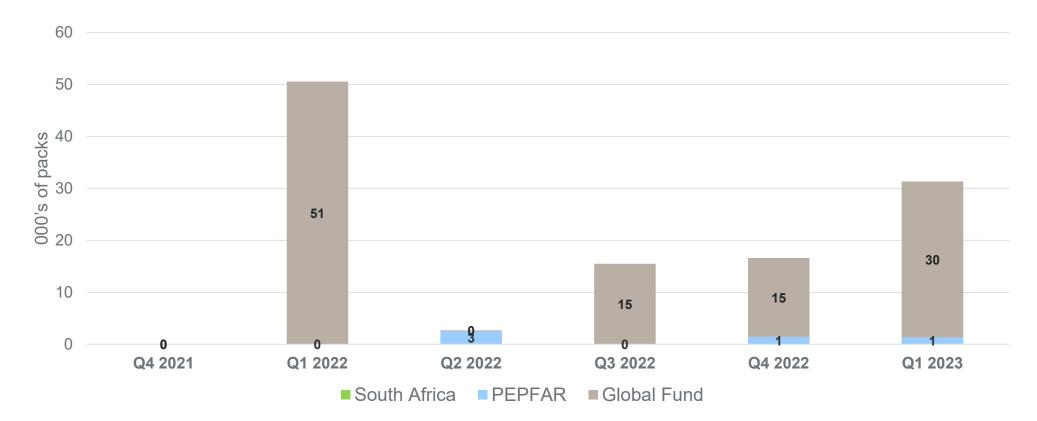
### LPV/r 40/10 MG ORAL GRANULES, 120 SACHETS





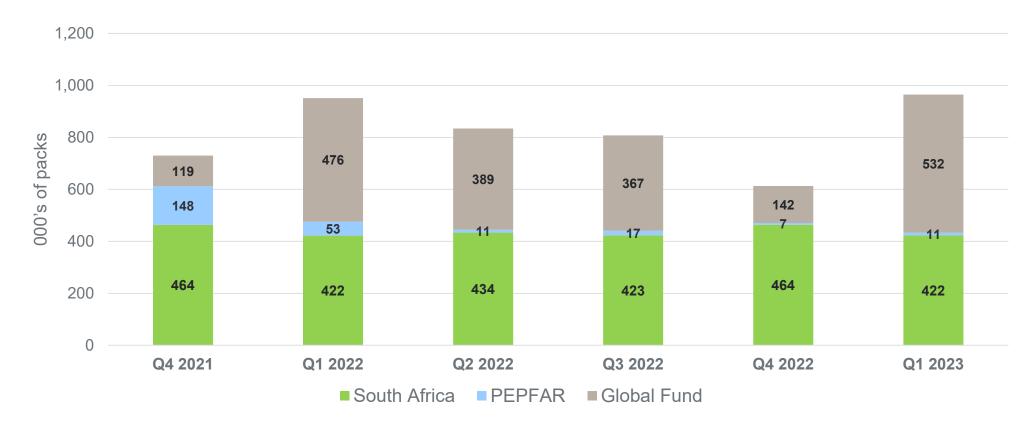
Source: Submissions from PEPFAR, Global Fund, South Africa, Ethiopia, Uganda Notes:

### LPV/r 40/10 MG ORAL PELLETS, 120 CAPSULES



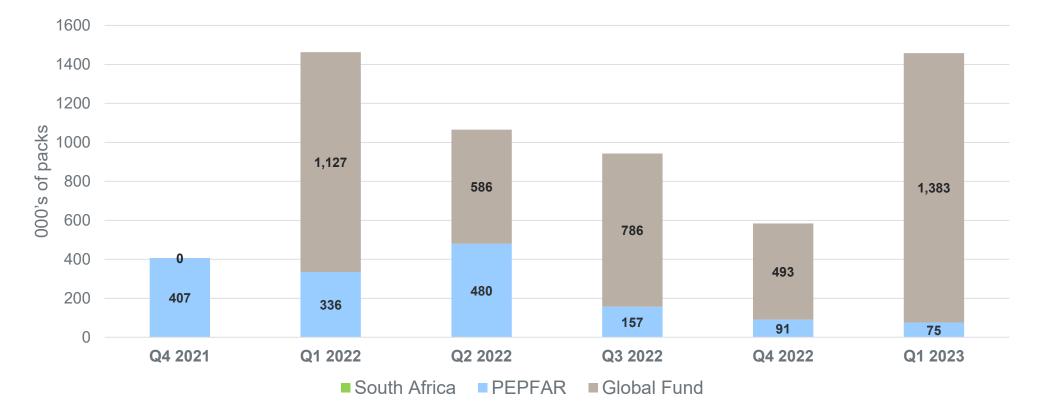


### ABC/3TC 600/300 MG, 30 TABLETS



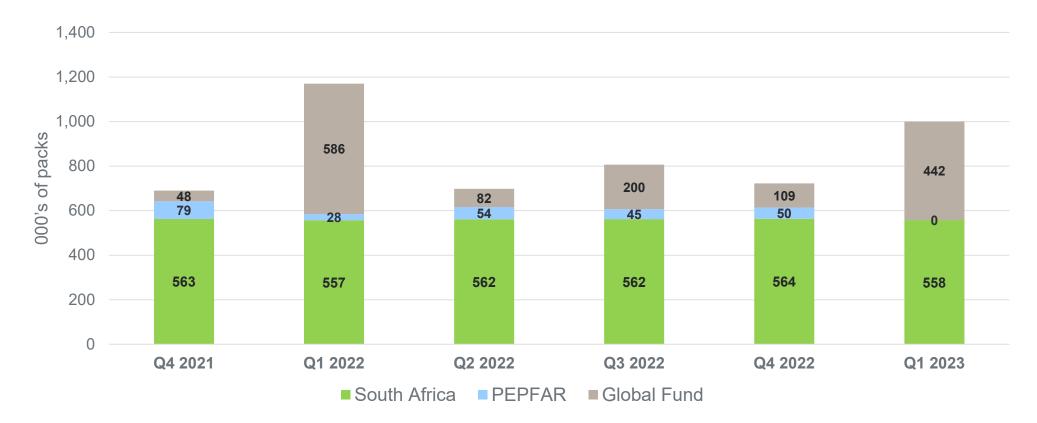


### ABC/3TC 120/60 MG, DISPERSIBLE 30 TABLETS



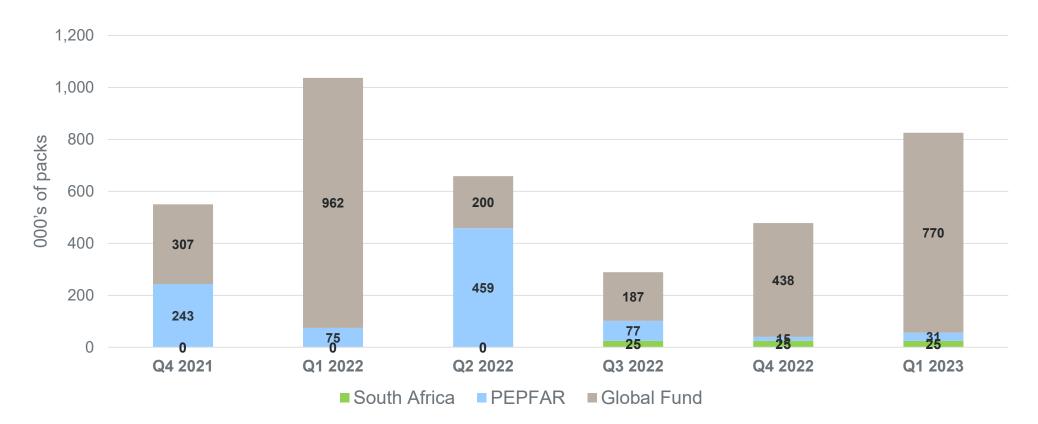


### AZT/3TC 300/150 MG, 56-60 TABLETS



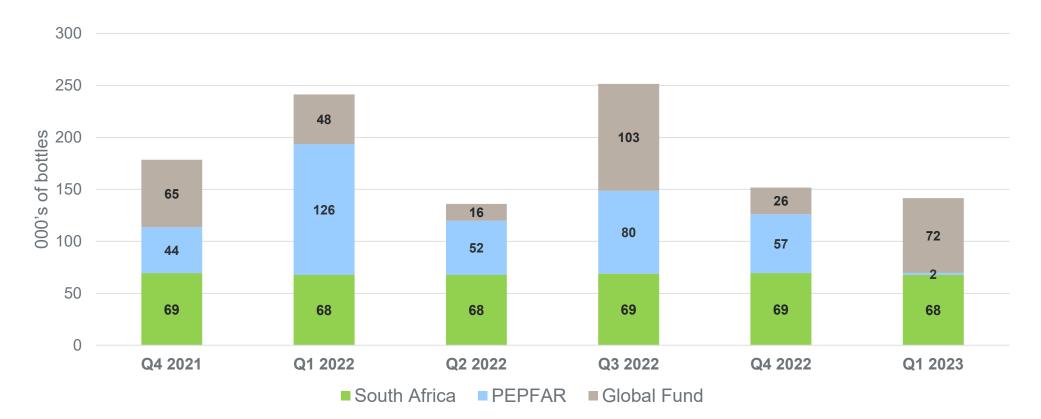


### ATV/r 300/100 MG, 30 TABLETS





### NEVIRAPINE 10 MG/ML ORAL SUSPENSION, 100 ML







የዜንች ጤና ስሃፖር ብልጽ ማና!



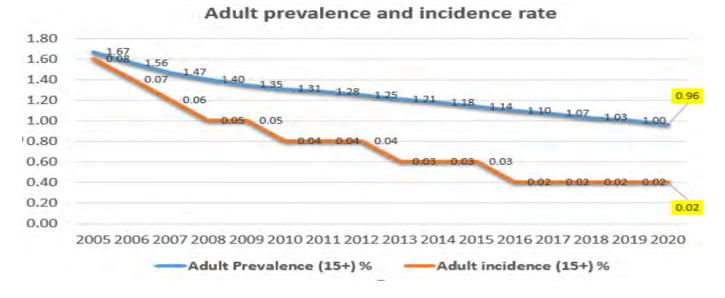


## Annual ARV Buyer and Seller Summit

Ethiopia's update on HIV Program and ARVs Procurement

# Country HIV/AIDS Program Update

- Ethiopia is a Federal State having ten regional states and two City Administrations
- In 2021, total projected population: 102,998,001 (CSA Projection)
- Annual New infections estimate in 2021 10,943
- Annual AIDS related deaths in 2021 11,673

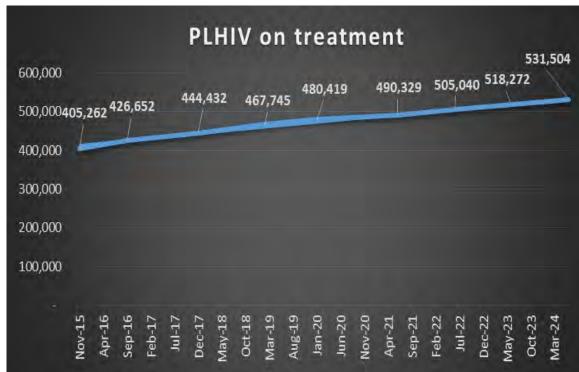


# Country HIV/AIDS Update continued. . .

- HIV/AIDS services is provided at
  - 1500 ART sites (>500second line sites, 50 Third Line sites)
  - 2865 PMTCT only sites
  - 14 Regional Laboratories
- The source of finance is The Global Fund, USAID/PEPFAR, Government
- National Program Owners and Implementers
  - MoH
  - FHAPCO
  - EPSA
  - EPHI
  - EFDA

## **DSD Models**

- ASM
- ■FTR
- UHEW managed CAG





# **Regimen Composition**

## Adult First Line

- 85% Adult on DTG Based Regimens
  - 84% on TLD
- Remaining 15% on EFV based regimens

## **Adult Second Line**

- 89% on ATV/r based PI Regimens
- 11% on LPV/r based PI Regimens

## **Adult Third Line**

DRV/r + DTG based regimens

## **Paediatrics**

- Previous shifts from AZT/3TC/NVP based regimens (80%)
- <20kg paediatrics on LPV/r based regimens
  - Shift planned to DTG 10
- >20kg on DTG based regimens



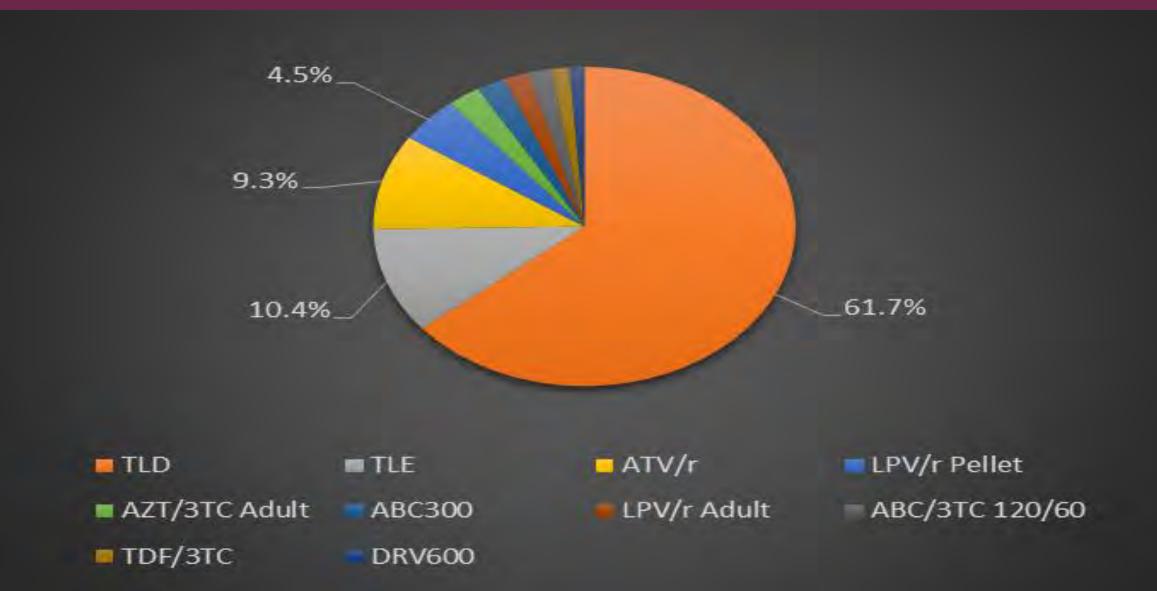


# Budget and ARV Procurements 2021/22





## Current ARV Procurement in Weight



# LTA Experience

- EPSA has conducted a three years long term agreement for selected ARVs with a contract end of November-2021
  - Review of suppliers performance
  - Best experience, challenges and lessons learnt from LTA
- Efficiency
- Reduction on workload
- Communication & Supplier responsiveness
- Lead time
- Possibility of price adjustment

- Restriction on the entry of new suppliers to the market
- Late contract termination
- COVID-19 Impact
- Consumption change



# **Planned Activities**

- New long term framework agreement contract for ARVs for 2022-2025
- Introduction of e-GP
- Continuing suppliers performance review
- Enhancing suppliers' relationship management
- Supplier and commodity positioning
- Country specific ARV suppliers forum





## **Annual ARV Buyer Seller Summit**





*Empowered lives. Resilient nations.* 

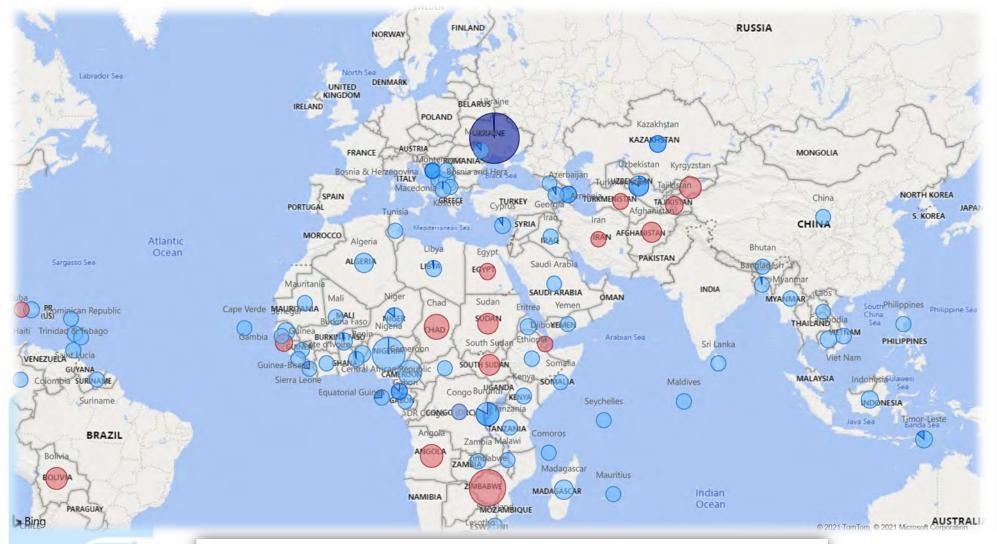
## **UNDP Procurement update**

ZAFAR YULDASHEV, Procurement Specialist, GF HIST, Copenhagen

> 13 October 2021 Denmark

## **UNDP Portfolio Overview**





**Type** • COVID-19 • Global Fund PR • Health Procurement • Health Procurement done by CO

UNDP Global Health Procurement and Supply Chain Management Overview

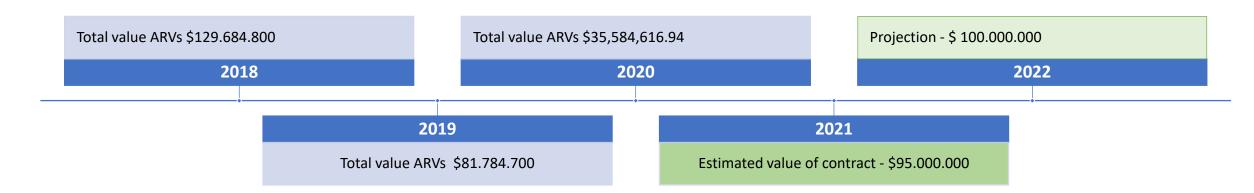
US\$ 304.1 Million 2020 Health Procurement Expenditure Delivered

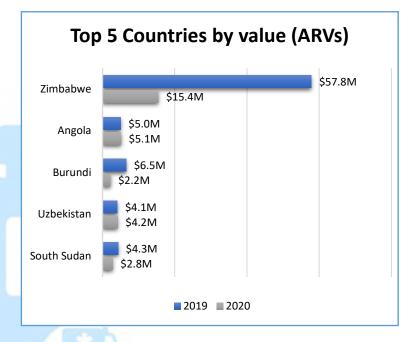
**40+ Countries** Health Procurement Support and Advisory

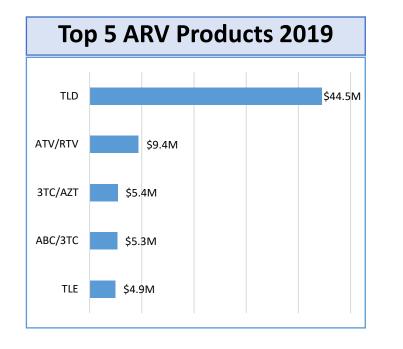
**100+ Countries** COVID-19 Emergency procurement support

# **ARV VOLUMES**





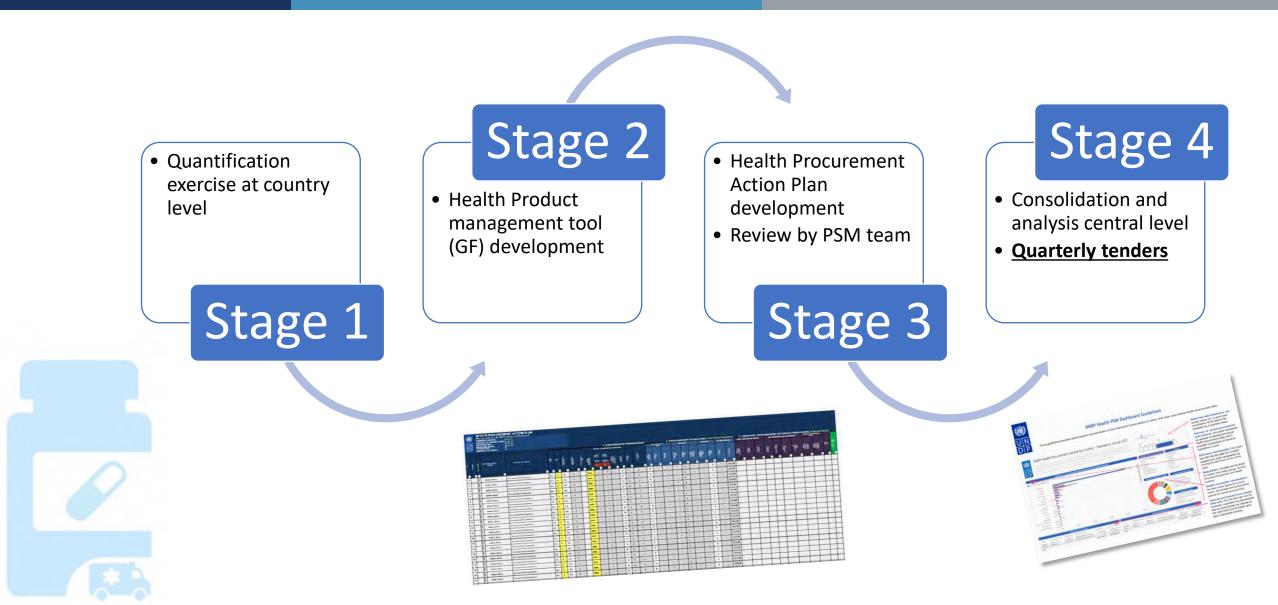






## **Planning and consolidation**

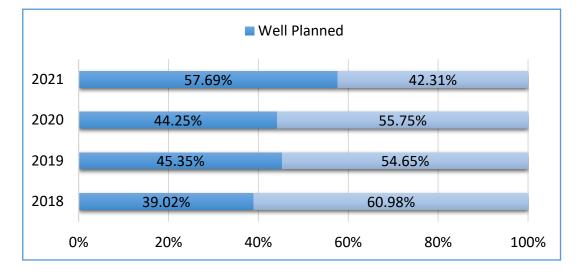




**Optimizations** 



- Centralized Procurement of key categories (consolidation and execution)
- Quarterly tenders for all product categories (# tenders, fixed schedules, predictability, better prices etc).
- Quarterly calls with LTA holders (feedback, KPI)
- Online delivery tracking



## Challenges



- Longer lead times availability of containers (MMD)
- Timely pick up of ARVs (e.g. GL, custom clearance)
- Delays of delivery due to shortage of API / QC test results
- Share quarterly forecasts
- Issuance of POs (availability funds)
- Ad-hoc requests to prevent stock out situations
- Non consistent inclusion data loggers in all shipments
- Payment process for "sanctioned" countries







- This is as a globally established, recognized and adaptable measurement tool for policy makers, manufacturers, suppliers, procurers, and healthcare facilities end users.
- This tool provides incentives for partners to improve their environmental and social sustainability record.
- It comprehensively monitor (I) Greenhouse gas emissions, (II) resource depletion (water, energy and material consumption), (III) chemical/toxic impact on human health and the environment, and (IV) human, labour rights and gender equality."

## Who is the SPIH for?



Suppliers – complete the appropriate SPIH Tool (general or pharmaceutical) for the product selected Buyers/Procurers – review the SPIH tool completed by a supplier for the product selected. Wholesalers: who operate as both a buyer and supplier and may be required to answer the SPIH, or could ask their suppliers to do the same

UN and Non-Government Organisations (non-buyer role): Provide the evidence to support robust policy positions

Regulatory agencies and policy makers: Set top-level policy on sustainability **Research bodies:** who could support best practice, provide new ideas and innovations at both company and product level; provide knowledge transfer to the market; &

Other standards bodies: develop robust standards/guidance that helps achieve specific goals; develop products that support standards users in achieving their goals; provide an independent view and rigor in demonstrating performance.

## What does it Measure: Key theme areas

#### **GHG Emissions**

- Governance
- Measurement
- Target setting
- Supply chain issues

Chemicals and Toxicity

- Management
- Restricted substances
- Disclosure

#### **Resources Depletion**

- Governance
- Manufacturing
- Supply chain issues

#### **Social Dimensions**

- Policy and governance
- Audits
- Equality issues

For more information, please visit <u>https://savinglivesustainably.org/</u>

## List of products covered by LTAs



Product description	Strength	Dosage form	Type of packaging*
Abacavir	300 mg	Tablet	Bottle HDPE: 60
Abacavir/Lamivudine	600 mg + 300 mg	Tablet	Bottle HDPE: 30
Atazanavir/Ritonavir	300 mg + 100 mg	Tablet	Bottle HDPE: 30
Darunavir	600 mg	Tablets	Bottle HDPE: 60
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate	50mg+300mg+300mg	Tablet	Bottle HDPE: 30
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate - cartoon less**	50mg+300mg+300mg	Tablet	Bottle HDPE: 30
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate	50mg+300mg+300mg	Tablet	Bottle HDPE: 90
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate - cartoon less**	50mg+300mg+300mg	Tablet	Bottle HDPE: 90
Dolutegravir	50 mg	Tablet	Bottle HDPE: 30
Darunavir/Ritonavir	400 mg + 50 mg	Tablet	Bottle HDPE: 60
Darunavir/Ritonavir	400 mg + 50 mg	Tablet	Bottle HDPE: 120
Efavirenz	600 mg	Tablet	Bottle HDPE: 30
Efavirenz/Emtricitabine/Tenofovir disoproxyl fumarate	600 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Emtricitabine/Tenofovir disoproxyl fumarate	600 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 90
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate	400mg+300mg+300mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	400mg+300mg+300mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	400mg+300mg+300mg	Tablet	Bottle HDPE: 90
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 90
Emtricitabine/Tenofovir disoproxyl fumarate	200 mg + 300 mg	Tablet	Bottle HDPE: 30
Lamivudine	150 mg	Tablet	Bottle HDPE: 60
Lamivudine/Nevirapine/Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 60
Lamivudine/Tenofovir disoproxyl fumarate	300 mg + 300 mg	Tablet	Bottle HDPE: 30
Lamivudine/Zidovudine	150 mg + 300 mg	Tablet	Bottle HDPE: 60
Lopinavir/Ritonavir*	200 mg + 50 mg	Tablet (heat stable)	Bottle HDPE: 120
Nevirapine	200 mg	Tablet	Bottle HDPE: 60
Raltegravir	400 mg	Tablet	Bottle HDPE: 60
Ritonavir	100 mg	Tablet	Bottle HDPE: 30
Tenofovir disoproxyl fumarate	300 mg	Tablet	Bottle HDPE: 30
Abacavir/Dolutegravir/Lamivudine	600 mg + 50 mg + 300mg	Tablet	Bottle HDPE: 30





### THANK YOU!!!

### zafar.yuldashev@undp.org

**UNDP Global Fund Health Implementation Support Team** 



#### Transforming Rwanda Medical Supply Chain Activity: Partnering with a local, commercial supply chain operator

Annual ARV Summit, October 2021

Dessalegn Tesfaye, Sr. Supply Chain Advisor, USAID/Rwanda, email: dtesfaye@usaid.gov



### **Outline of Presentation**

- Introduction to the Rwanda Medical Supply Ltd (RMS) & Transforming Rwanda Medical Supply Chain (TRMS).
- Objectives of TRMS activity
- USAID/Rwanda Local Supply Chain Partner Transition strategies
- Milestones of transitioning procurement services to local partner (RMS)
- Lessons learned

#### **TRMS Contract Signing Event**



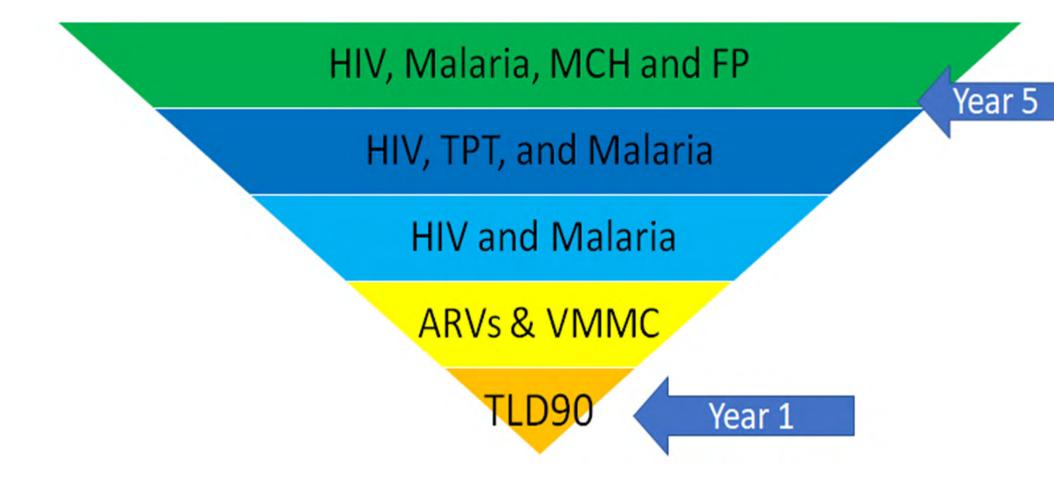
### Objectives of Transforming Rwanda Medical Supply Chain Activity

- Strengthen planning and management capabilities to support the transition from a national commercial parastatal towards a selfreliant, private sector supply chain organization
- Improve operational efficiencies through the application of global industry standards for procurement, warehousing and in-country distribution
- 1. Improve Supply Chain **Data Quality and Use for Decision Making** at all levels to **optimize supply and improve order fill rates.**

# USAID/Rwanda used a stepwise approach. Including

- Support national reforms to create commercial supply chain operator -RMS
- Two prong approach @ RMS (a) receive TA through PSM and/or NextGen and (b)key personnel implement/manage the USAID/TRMS activity
- Innovative contracting with broad umbrella instrument with defined task orders
- Start with focus on a single program area and commodities (HIV/AIDS)
- Start with programs and commodities that RMS has experience procuring
- Involve all stakeholders especially the GFATM, GOR and USAID's implementing partners

#### **Milestones for Expanding Range of Commodities**





## **Initial Lessons Learned**

Some of the lessons that may help other countries to consider in the planning are as follows:

**Step 1**: check the capability of the local partner(a) that it has functional capacity, and (b) that it can modify its procurement manuels & financial management systems. Document it.

**Step 2**: involve all stakeholders in the planning (internal, GFATM, govt, partners, private sector, and FBO)

**Step 3**: use & actively engage USAID/W available resources on QA/QC, ADS 312, other experiences

Step 4: design a feasible contract and identify all the resources to implement it

**Step 5:** manage expectations, collect regular data through Third Party Monitoring, and adopt a stepwise approach

Rwanda is implementing its transition plan to local partners and such forums are important to share sourcing and marketing of ARVs.





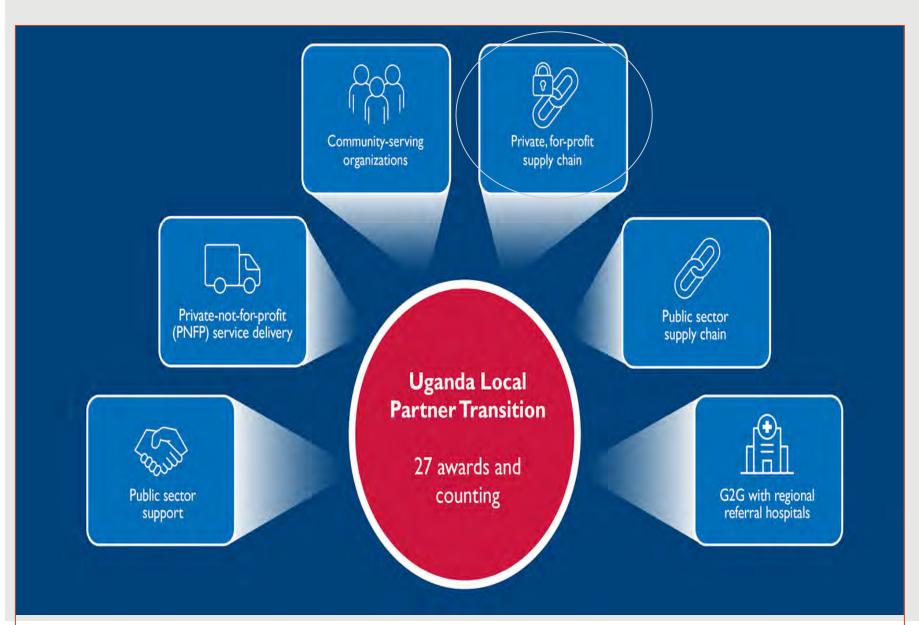
# USAID/Uganda - HIV Commodity procurement for the PNFP Sector

Presented by: <u>Suzan Nakawunde</u>, USAID/Uganda, PMS-Health Commodities

#### **Presentation Outline**

- Background to local partner transitions
- Procurement transitions in Uganda
- New Local procurement Agents
- Risk Management
- Collaboration with other key players

#### Engaging a Diversified Ugandan Partner Base for Local Transition



#### **Procurement transitions in Uganda**

- Commodity procurement IDIQ is implemented progressively.
- Emphasis on building the capacity of local partners

GOU

YR5 (100) COP24

TBD

YR4(100%)

YR3(75%)

COP22

TBD

COP23

TBD

Preparing host government to take over

YR2(50%)

COP2

\$30M

YR1 (25%)

COP20

\$8.6M

#### Uganda's new Procurement Agents

- The Request for Proposals (RFP) resulted in two successful IDIQ Offerors:
- Joint Medical Stores (JMS) and
- 2) Medical Access Uganda Limited (MAUL) to procure 5 categories of HIV commodities
- IDIQ TEC \$294M over 5 years
- Year One, TOI implemented by Joint Medical Stores
   I<sup>st</sup> line ARV TLD 90packs 298,000 packs
   2<sup>nd</sup> Line ARV ALD 30 packs 142,000 packs

#### **Risk Management**

- **Phased transition** to local agents away from the centrally managed mechanisms.
- Competitive process at the task order level.
- IDIQ holders partnered with International Organizations for capacity building and better understanding of USAID policies.
- IDIQ holders are required to work with the GHSC/QA-FHI360 to guarantee quality of products.
- Task Order have included Payment Milestones.

#### Collaborating with Other Key Stakeholders

- Nationally:
  - a) Ministry of Health
  - b) USG Above site Supply chain partner
  - c) National Drug Authority Pharmacovigilance issues
- Other donors e.g. Global Fund/UNITAID/CHAI
- GHSC-PSM/RTK align deliveries/sharing of experiences
- GHSC-QA Quality Issues
- Last mile delivery through a 3PL transportation to Service Delivery Points
- Regional Service Delivery Partners consumption trends

### Thank you







# PEPFAR Priorities for COP 2022

S/GAC Katy Godfrey S/GAC Hilary Wolf S/GAC Sara Klucking S/GAC Kanjinga Kakanda

October 14, 2021

**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

- Priorities for Adult Treatment
- Priorities for Pediatric Treatment
- Priorities for Prevention
- Priorities for Tuberculosis Preventive Treatment (TPT)







## **Priorities for Adult Treatment**

S/GAC Katy Godfrey

October 14, 2021

**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

#### Major themes

- Dolutegravir as both first-and second line therapy
- Differentiated service delivery and multimonth dispensing
- Focus on lifespan and healthspan
  - Advanced disease
  - Aging cohort.

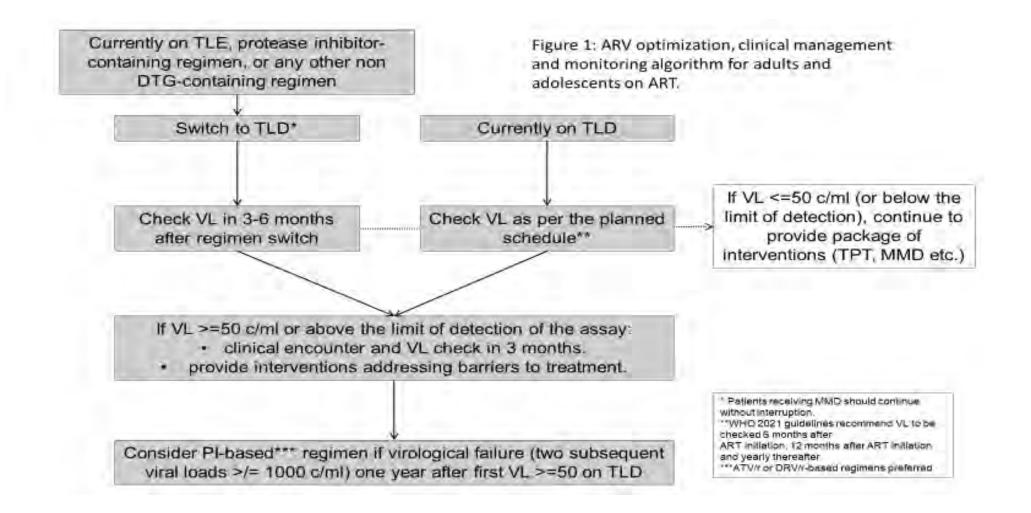


#### Dolutegravir for suppressed individuals

- TLD as the preferred option for ART for both first and second line treatment (for all PLHIV >=30kg including adolescents and pregnant and breast feeding women)
- Complete scale up of DTG to all individuals including those suppressed on PI and NNRTI based regimens
- Weight gain documented in multiple studies, I
  - AFRICOS was clinically small but statistically significant
  - Likely multifactorial
- Drug drug interactions:
  - Rifampin requires extra dose
  - EFV/PIs-requires extra dose
  - Metformin: significantly increased metformin exposure
  - Prenatal vitamins, Ca++ containing antacids- dose spacing



#### Approach to non suppression: any vI >50 c/ml





**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

#### DTG for unsuppressed individuals

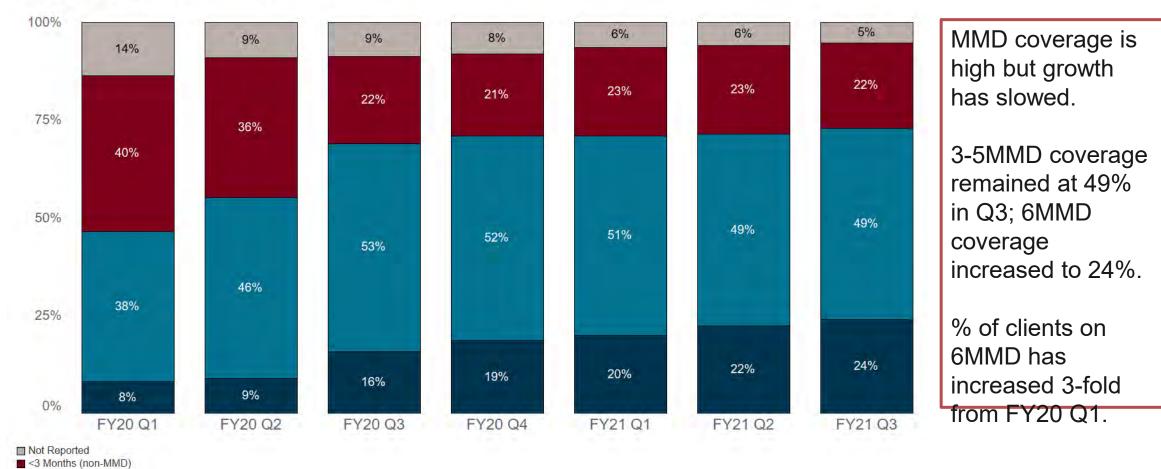
- Viral failure: 2 consecutive VL > 1000 c/ml
- Viral non-suppression: Any measurable viral load above 50 copies/ml (or above the limit of detection of the test used.
- Low level viremia: Repeated viral loads that are measurable but under 1000/c/ml



#### Differentiated Service delivery and multimonth dispensing

- Separation of drug delivery and clinical care
- All individuals should get 3 months, preferably 6 months of drug
- Decentralized delivery-using other pick-up points besides clinic pharmacy
- Delivery of other required meds including ARVs
  - HIV related eg Cotrimoxasole, TPT
  - Non-HIV related: in setting of COVID-19 PEPFAR permissive for delivery of other meds.



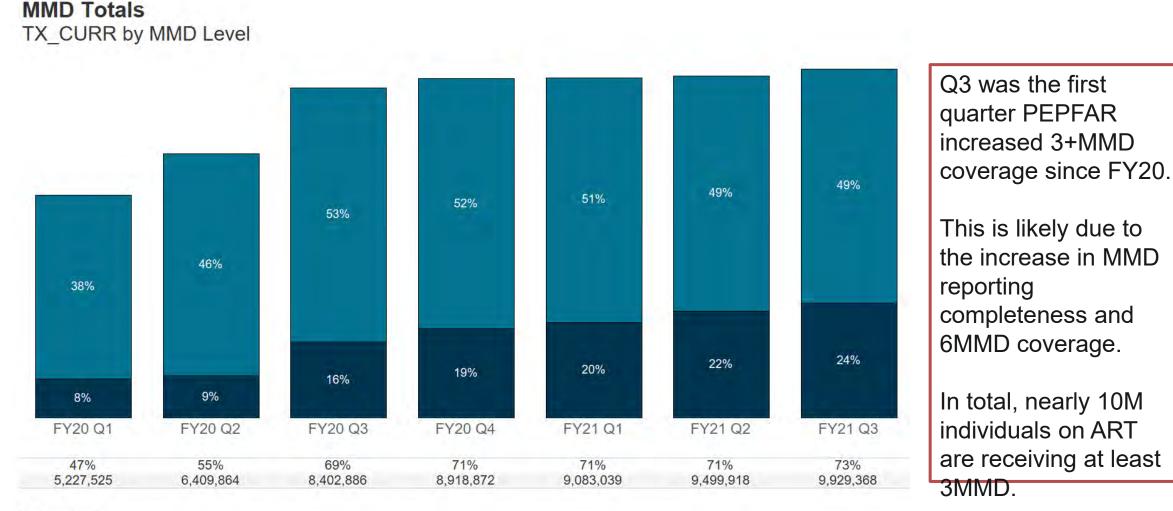


#### MMD Breakdown TX\_CURR by MMD Duration

3-5 Month MMD
 6+ Month MMD

South Africa not included

## MMD coverage and # of clients on MMD



3-5 Month MMD
 6+ Month MMD

South Africa not included

#### Comments

- COVID adaptation that is here to stay
- May have reached saturation
- Ordering patterns have changed; more stock required in country



#### Focus on mortality-advanced disease

Persistent problem for PEPFAR

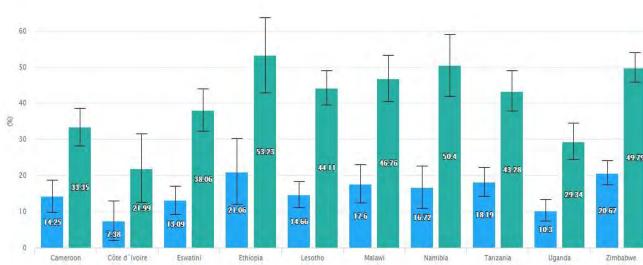
Individuals presenting late, or representing to care

Interventions are life saving:

• TPT

Diagnose and treat cryptococcal disea

Cotrimoxazole



The PHIA Project

#### Late HIV Diagnosis

Cameroon (CAMPHIA 2017), Côte d'Ivoire (CIPHIA 2017), Eswatini (SHIMS 2 2016), Ethiopia (EPHIA 2017), Lesotho (LePHIA 2016), Malawi (MPHIA 2015), Namibia (NAMPHIA 2017), Tanzania (THIS 2016), Uganda (UPHIA 2016), Zimbabwe (ZIMPHIA 2015)

Age Range: 15-49 years / Gender: Total / Stratification: No stratification

Among persons who tested HIV positive in the PHIA survey but self-reported HIV negative, percentage who had a CD4 cell count < 200 cells/ml and < 350 cells/ml, by sex and selected demographic characteristics. All percentages are weighted. Estimates with an asterisk are based on a very small number (less than 25) of unweighted cases and have been suppressed.

Percentage < 200 cells/µL</li>
 Percentage < 350 cells/µL</li>



**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

#### Cryptococcal disease

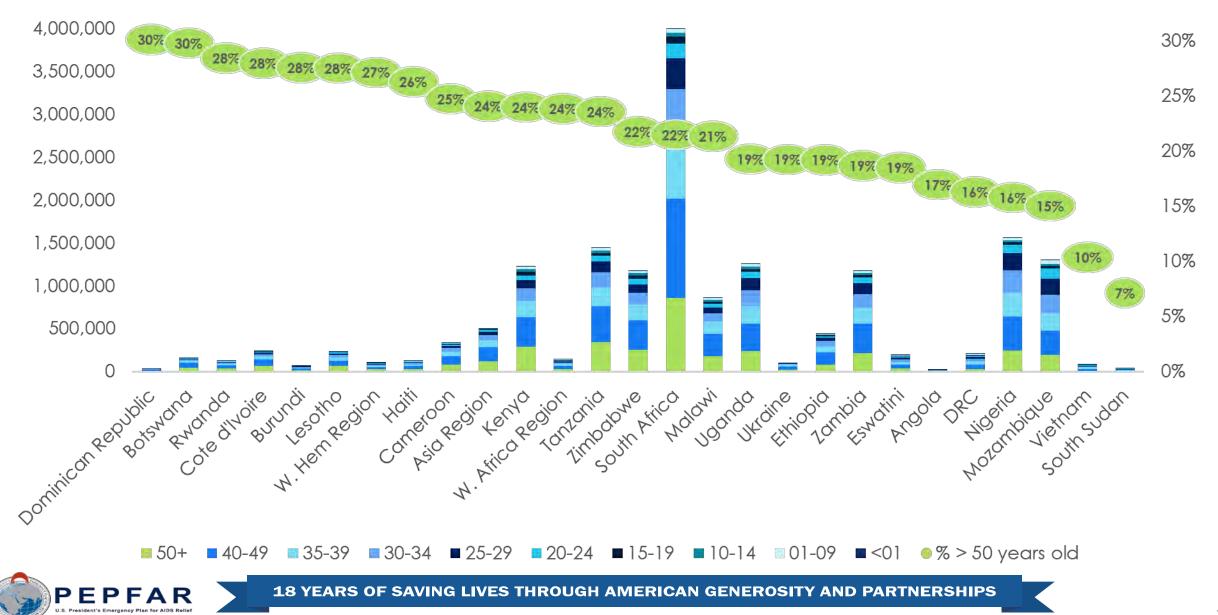
- Preemptive treatment: CrAg + but LP negative: Fluconazole
- Meningitis treatment: AmB with flucytosine preferred, followed by fluconazole
  - New study showing efficacy of a single dose of liposomal AmB plus flucytosine
  - Should that become part of WHO guidance, PEPFAR will consider.

Flucytosine is biggest challenge

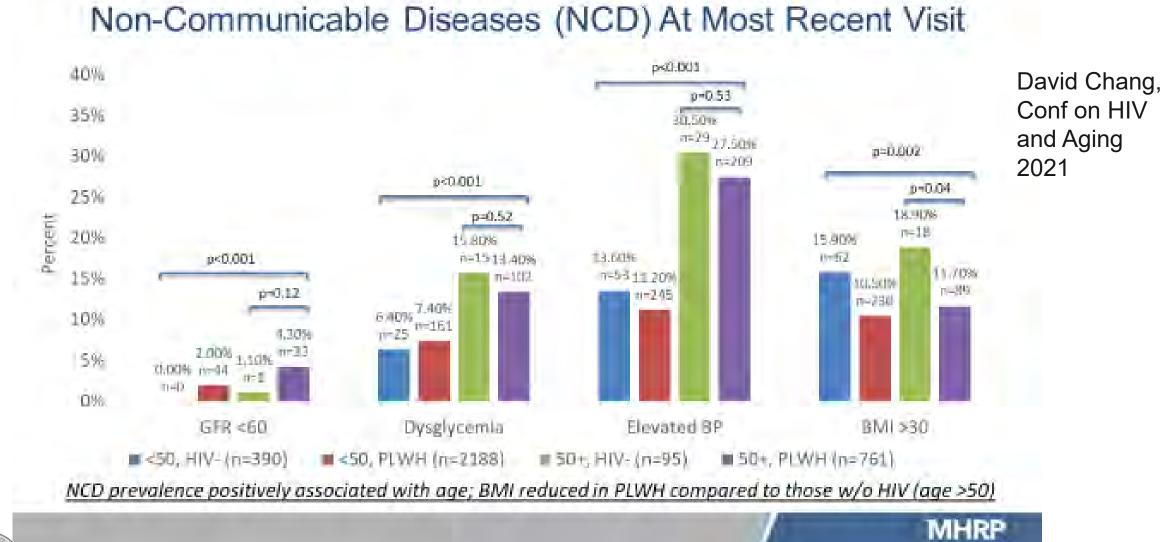


## Focus on Mortality: Aging





#### Aging and comorbities-high burden of disease-AFRICOS



TEARS OF SAVING LIVES THROUGH AWERICAN GENERUSH I AND FARTNERSHIP

EPFAR

#### Client centered care

- PEPFAR does not support screening and treatment of co-morbid disease
- Can support delivery of medicines for older individuals if relevant.



**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 





# **Priorities for Pediatric Treatment**

S/GAC Hilary Wolf

October 14, 2021

**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

#### PEPFAR Treatment Cascade for CLHIV <15

PEPFAR

esident's Emergency Plan for AIDS Reli



**18 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS** 

90/90/90 cascade (data are presented for the last 4 quarters)



### CLHIV should undergo DtG 10 mg dispersible tablets manufactured by Macleods (Photo Credit: CY Malati. 2021) **Single substitution** to DTG as soon as DTG is available in country



### DTG 10 mg supply planning

- USG, through PEPFAR, expects that all countries will transition all CLHIV onto a DTG-based regimen as quickly as possible; full implementation should be completed or at least well underway in COP21
- Detailed supply planning is extremely important to achieve a prompt transition and help ensure the roll out of DTG is not hindered by over-supply of pediatric LPV/r
- New orders for LPV/r will be highly scrutinized to ensure procurement is limited to quantities needed for alternative treatment only (expect to be <10% of CLHIV)</li>



Photo Credit: USAID Global Health Supply Chain, 2018



Photo provided courtesy of Viatris, 2021



### Clinical recommendations for transition to DTG based regimen

- Rapid programmatic transition to DTG-based regimens for ALL children (at least 4 weeks old and 3kg) new to ART and established on ART irrespective of their current regimen.
- Single switch can and should occur irrespective of the availability of a VL test/result or the value of the latest VL result
- Important to maintain or optimize children on an ABC/3TC backbone
- Patients previously receiving MMD should continue on MMD when the switching to DTG



TRANSITIONING TO THE 2021 OPTIMAL FORMULARY FOR ANTIRETROVIRAL DRUGS FOR CHILDREN; IMPLEMENTATION CONSIDERATIONS JULY 2021



THE 2021 OPTIMAL FORMULARY AND LIMITED-USE LIST FOR ANTIRETROVIRAL DRUGS FOR CHILDREN





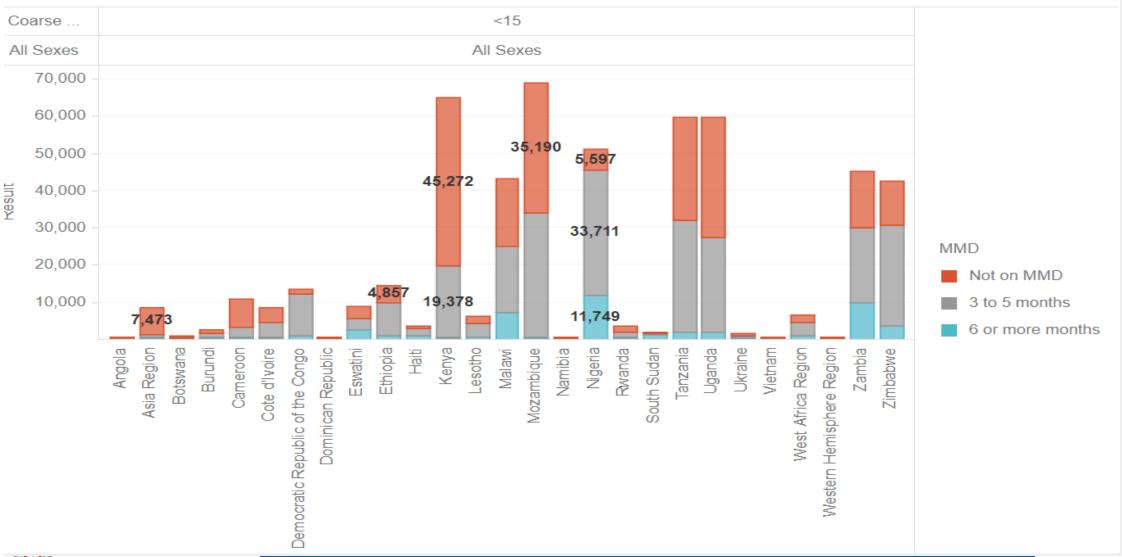
### Pediatric MMD guidance in the setting of COVID-19

- Programs should make every effort to supply children and CLHIV/ALHIV initiating and refilling ART with a 3-month supply of ARVs for those 2 - < 5 yo and a 6-month supply for those > 5 yo.
- For children requiring Cotrimoxazole, a 3-6-month supply should be provided at the same time as ARV pickup
- For children starting a new medication, administration of the first dose should be demonstrated and administered in clinic
- HIV-exposed infants should be given the greatest quantity of infant prophylaxis, both ART and cotrimoxazole as possible to last until the next immunization or EID testing appointment



### MMD for CLHIV<15 in Q3 (April 2021-June 2021) by country

#### Clients receiving multi-month dispensing by Age/Sex









## **Priorities for Prevention**

S/GAC Sara Klucking

October 14, 2021

### PrEP Use Trends are Encouraging

Fiscal Year	2019	2019	2019	2020	2020	2020	2021	2021	2021
Operating	Result	Target	%	Result	Target	%	Result	Target	%
Unit	Cumulativ		Achievem C		1	Achievem (			Achievem
<u> </u>	e	0.000	ent	e	0.440	ent	e	10,100	ent
Asia Region	4,155	2,393	173.6%	5,930	8,110	73.1%	7,665	13,199	58.1%
Botswana	1,247	999	124.8%	1,301	1,001	130.0%	6,378	6,366	100.2%
Burundi							121	2,000	6.1%
Cameroon	208	2,077	10.0%	1,165	1,083	107.6%	1,751	7,096	24.7%
Cote d'Ivoire				422	1,810	23.3%	1,114	7,265	15.3%
DRC				1,383	1,910	72.4%	3,230	11,012	29.3%
DR	409	450	90.9%	710	700	101.4%	595	1,849	32.2%
Eswatini	3,025	3,268	92.6%	8,419	4,479	188.0%	10,416	11,760	88.6%
Ethiopia	314	0		2,446	2,601	94.0%	9,874	14,046	70.3%
Haiti	111	1,000	11.1%	2,759	3,566	77.4%	5,575	4,244	131.4%
Kenya	34,110	31,047	109.9%	39,841	37,947	105.0%	61,762	99,979	61.8%
Lesotho	12,143	12,429	97.7%	11,251	18,460	60.9%	13,898	20,895	66.5%
Malawi	762	1,060	71.9%	189	6,549	2.9%	2,574	16,052	16.0%
Mozambiq ue	3,504	7,049	49.7%	11,122	8,514	130.6%	25,727	54,834	46.9%
Namibia	10,583	4,553	232.4%	11,654	15,589	74.8%	13,902	21,335	65.2%
Nigeria	379	0		32,249	14,738	218.8%	96,897	102,094	94.9%
Rwanda	943	1,800	52.4%	2,094	1,398	149.8%	8,446	7,602	111.1%
South Africa	30,599	28,099	108.9%	63,673	117,957	54.0%	185,993	250,020	74.4%
Tanzania	5,312	3,971	133.8%	7,147	32,652	21.9%	29,272	183,174	16.0%
Uganda	17,825	16,841	105.8%	37,831	30,000	126.1%	86,131	95,785	89.9%
Ukraine	881	2,100	42.0%	1,266	981	129.1%	1,560	3,016	51.7%
Vietnam	4,854	5,610	86.5%	8,311	4,641	179.1%	12,907	24,149	53.4%
WAR							3,146	4,483	70.2%
WHR				954	112	851.8%	1,135	3,069	37.0%
Zambia	23,352	8,647	270.1%	45,934	20,329	226.0%	96,820	86,694	111.7%
Zimbabwe	8,736	3,292	265.4%	13,966	8,239	169.5%	25,652	22,799	112.5%
SUM	163,452	136,685	120%	312,017	343,366	91%	712,541	1,074,817	66%

For FY 2021, PEFPAR set an ambitious goal to provide PrEP to >1,000,000 people at substantial risk of acquiring HIV

- 9 out of 26 OUs >=75% achievement
- 9 out of 26 OUs < 50% achievement
- 25 out of 26 >=100% of last year's annual total at this 3/4 point this year



### OUs are scaling up PrEP across PEPFAR

- > One million on PrEP
- PrEP scale-up continues in COP 21 and onward
- PrEP continuation research is ongoing
- Guidance is encouraging multi-month dispensing of oral PrEP
- PEPFAR continues to evaluate the expansion of the product pipeline into the PEPFAR prevention programs



### ORAL TABLET, DAILY

- Emtricitabine/Tenofovir DF (TDF/FTC) 200/300 mg Tablet, 30 Tablets
- Lamivudine/Tenofovir DF (TDF/3TC) 300/300 mg Tablet, 30 Tablets
- Tenofovir 300 mg Tablets, 30 Tablets

### VAGINAL, MONTHLY

- Dapivirine Vaginal Ring
  - Sole Source Manufacturing
  - New to product commercialization



### LONG ACTING, VARIED ADMIN

- Long Acting Injectable Cabotegravir
  - One dose intramuscularly every two months
- Islatravir
  - Oral tablet, monthly tablet
- Lenacapavir
  - Twice yearly injection

### ORAL TABLET, DAILY

- Dual Prevention Pill for HIV and Pregnancy Prevention
  - Tenofovir Disoproxil Fumarate (TDF 300 mg), Emtricitabine (FTC 200 mg), Levonorgestrel (LEVO 0.15 mg) Ethinyl Estradiol (EE 0.03 mg), Fixed Dose
  - Combination Tablet, 28 Tablets 21 tablets of TDF/FTC/LEVO/EE and 7 tablets of TDF/FTC







## Priorities for Tuberculosis Preventive Treatment (TPT)

S/GAC Bill Paul / Kanjinga Kakanda

October 14, 2021

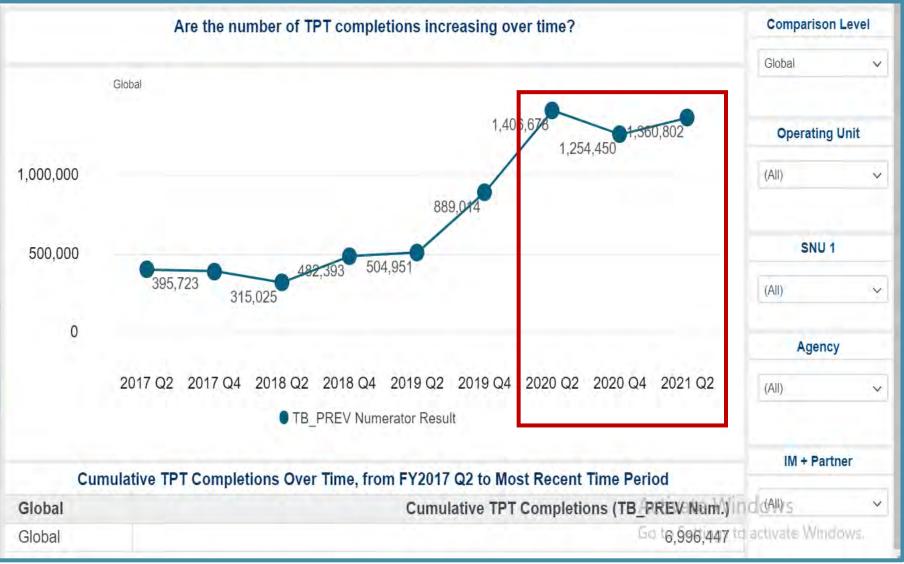
### TPT Scale-up Progress Across PEPFAR countries

- Ambitious targets set for full TPT coverage across PEPFAR countries since 2018
- More than 6,9 million have completed TPT since 2017 (about 40% of the current estimated TX\_CURR)
- Performance in <u>9 highest volume</u> OUs (>500,000 patients) accounting for 82% of PLHIV on ART:
  - 5 OUs have >50% TPT coverage
  - 2 OUs have >25% coverage
  - 2 OUs achieved <20%</li>

Year	TPT Targets	Results
FY18	1,900,000	797,418
FY19	2,800,000	1,393,965
FY20	6,300,000	2,661,128
FY21	6,686,627	1,360,802* (semi- annual results)



### Global Results for TPT coverage – Q2FY17 to Q2FY21



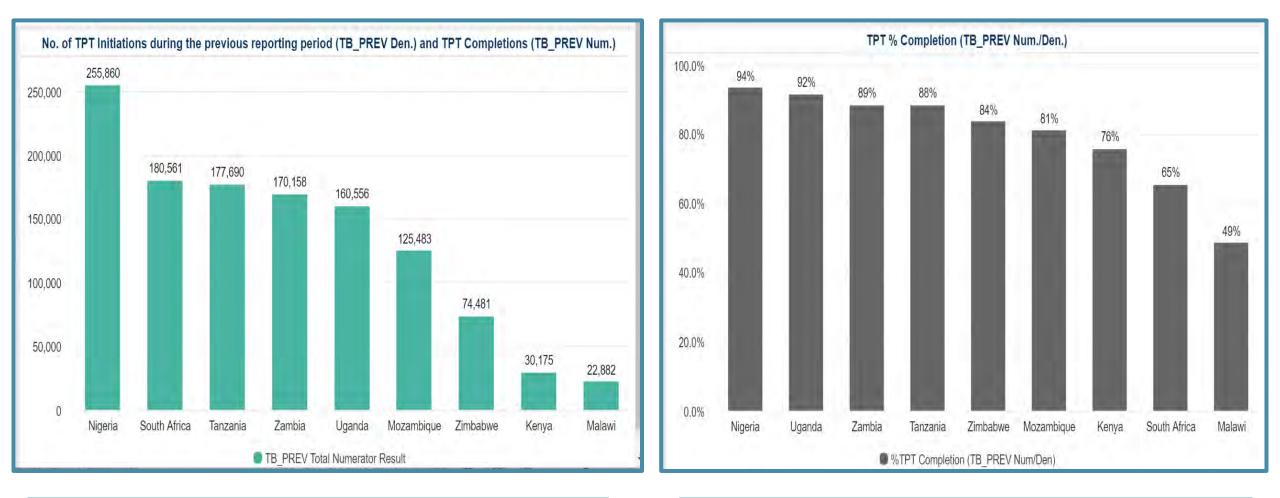
- Massive TPT scale-up observed from Q4 2019
- Upward trend sustained
- 57% of TPT results accomplished in the last 3 reporting periods
- Increased number TPT results maintained in 2020 despite COVID-19

### Service Continuity in COVID-19 Context

- COVID-19 innovations included rapid integration of TPT and TB treatment for PLHIV into existing DSD models, harmonized MMD for ARVs and TPT, TPT expansion in DDD (community sites, private facilities and pharmacies)
- Program adaptations resulted in great volume in TPT completion despite disruptions due to COVID-19,
  - Nigeria 56% of cumulative TPT coverage occurred in the last 3 quarters as a result of massive TPT initiation with completion over 90%
  - Tanzania impressive overall TPT scale with ~80% patients covered with a course of TPT (completion rate maintained at/or above 85% for the last 2 years)



# Recent TPT initiation/ Q4FY20 and completion/Q2FY21 (highest volume OUs) Results



**Maintaining strong TPT initiation** 

Great completion rates for 6 of the 9 high volume OUs



### Looking Forward

- PEPFAR committed to treating all eligible PLHIV with TPT, and reaching full TPT coverage by FY22
- TPT commodity availability is critical to respond to scale-up demand, and sustain MMD and DDD models being implemented
- Highlights from the recently published WHIP3TB study's results:
  - 3 months weekly of Rifapentine and Isoniazid (3HP) had higher TPT completion than daily isoniazid
  - No additional benefits (i.e., further reduction in TB incidence) from a second round of TPT
- Focus on shorter, Rifapentine based regimen (3HP, 1HP when available on the market) PEPFAR preferred TPT regimen is 3HP (Uptake for shorter regimen has been slower than anticipated in PEPFAR OUs due to various reasons, including COVID-19 related)
- TPT provision for child <5 yo contacts of PLHIV with TB remains a priority, but still a huge gap in uptake (child-friendly formulation needed)





U.S. President's Emergency Plan for AIDS Relief



USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM Procurement and Supply Management

# GHSC-PSM Reflections and Outlook for ARV Supply Chains

Alan Pringle, GHSC-PSM Supply Chain Director October 2021

Link to live presentation





# GHSC-PSM ARV COP20 Snapshot Summary

34% Delivered by Sea Increase of 7%

Ę

91% Avg Overall Supplier Performance Score Inclusive of all scorecard metrics (e.g., OTP, incidents, GSI, qualitative factors) \$405M ARVs Procured

93% OTD / 88% OTIF 89% / 84% COVID Impact Over last 4 quarters

MMD likely saved 59 million pharmacy trips for PLHIV\*



### ARVs Delivered to 32 Countries

**7% Pediatric ARV Spend** Representing 39% processed line items

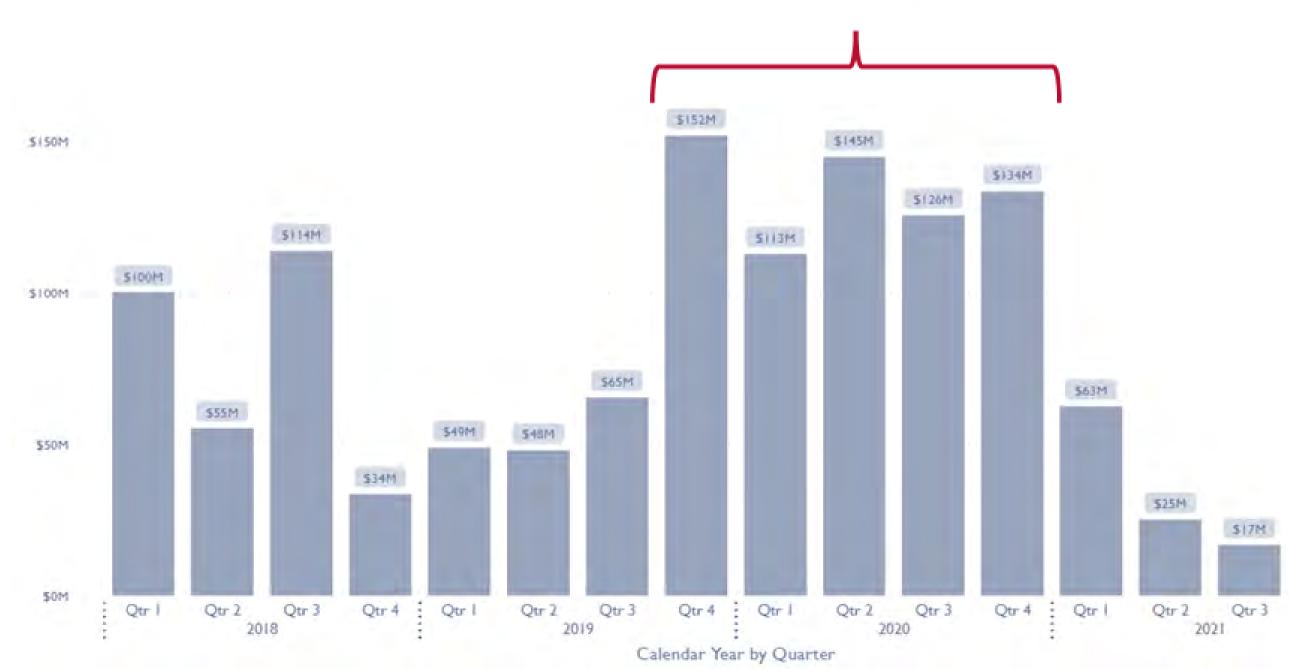


32% of Orders Fulfilled from the RDC 8 unique products

> Data as of August 2021 \*Life of project through June 2021

# PEPFAR Countries were Encouraged to Accelerate Orders in 2020 to Offset COVID-Related Supply Chain Risks

Order Placement Date: Date PO is released to vendors. Includes orders for both Direct Drop and for the RDCs



Data as of August 2021

# Adoption of Global Standards for Product Identification, Data Capture and Master Data Exchange



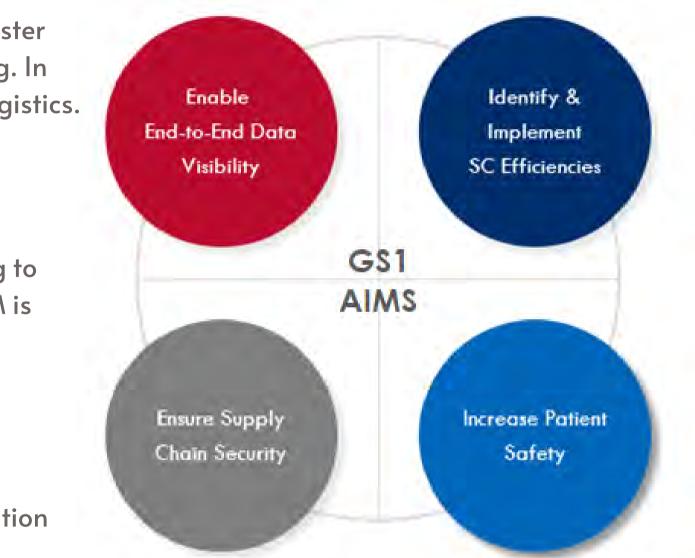
GSI-based product and location identifiers (GTINs & GLNs) and product master data exchanged via GDSN supports the population of the GHSC-PSM catalog. In turn, catalog data is used for supply chain processes from procurement to logistics.



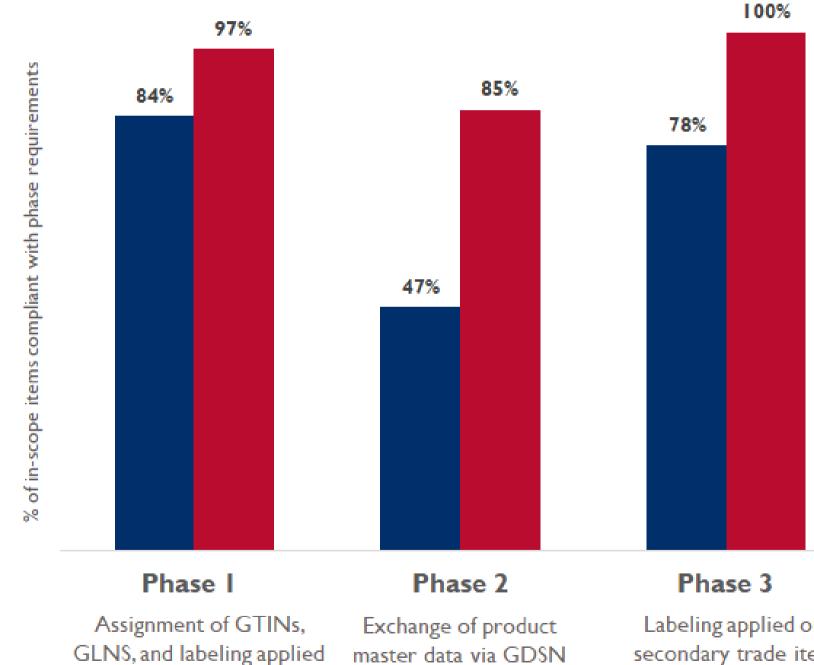
As countries progress toward using standards-based identifiers and labelling to support in-country operational activities and product traceability, GHSC-PSM is receiving increasing requests to provide GTIN data and confirm presence of product labelling to support those activities.



Through advancing the adoption of standards-based identifiers and serialization GHSC-PSM continues to work towards increased supply chain visibility and traceability.

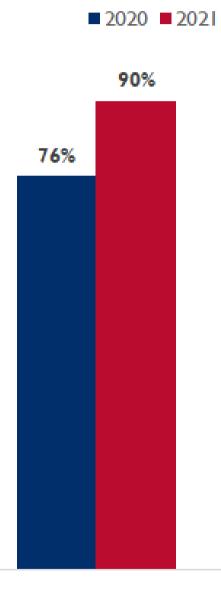


# **ARV GHSC-PSM Global Standards Requirement** Compliance from October 2020 to September 2021



on tertiary packaging

Labeling applied on SSCC applied to logistics unit and serialization secondary trade item packaging applied to trade items



#### Phase 4

# Evolving GHSC-PSM's Procurement Strategy

**GHSC-PSM ARV Landscape** 



Catalog Consolidation





**Increased Supply Chain Flexibility** 



### Differentiators

- Extended Shelf-life
- Price
- Packaging Efficiencies
- E2E Visibility
- Increased PSE In-country (e.g., DAP, VMX)

#### USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

# Thank you!





### **ARV Large Buyer Seller Summit**



### **Republic of South Africa**



**Ms Khadija Jamaloodien** Affordable Medicines Directorate



ARV Large Buyer Seller Summit October 2021

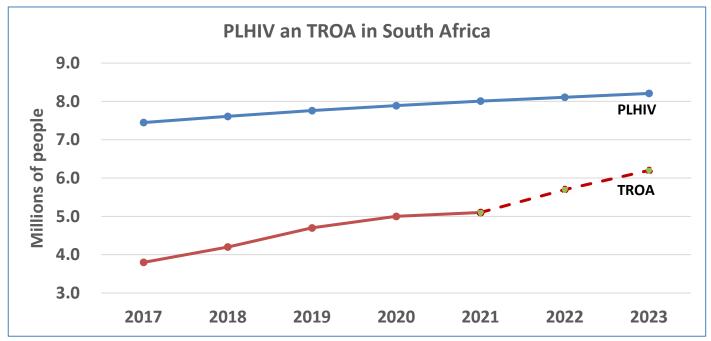


Department: Health REPUBLIC OF SOUTH AFRICA



### We expect continued patient growth in SA

PLHIV will surpass 8m in 2021, and SA still retains its aim to grow TROA to 6m



#### Note

- TROA = Total remaining on ART
- TROA data on graph excludes private sector
- PLHIV from Thembisa 4.4 model



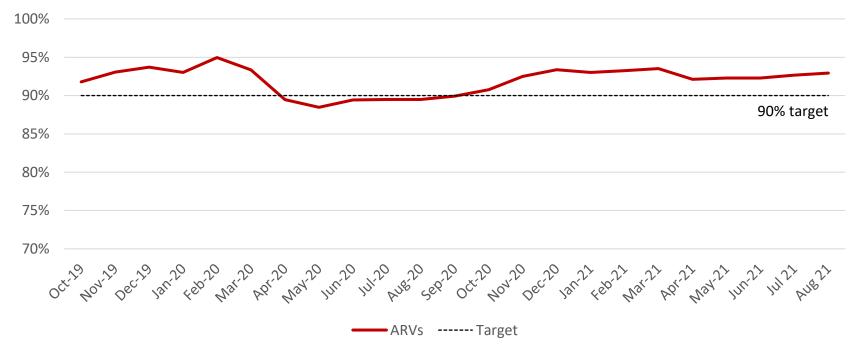
**REPUBLIC OF SOUTH AFRICA** 



### ARV availability maintained >90% apart form short period over COVID 1<sup>st</sup> Wave



**ARV** Availability



#### Note

- TROA = Total remaining on ART
- TROA data on graph excludes private sector
- PLHIV from Thembisa 4.4 model



**REPUBLIC OF SOUTH AFRICA** 



#### **ARV** Tender



- Current tender expires on 30 June 2022
- New tender for 3 year period from Jul-22 to Jun-25
- Bids have been received
- Evaluation underway
- Targeting announcement of award in Feb-22
- AMD will work with suppliers on transition







### Transition to dolutegravir based regimens



#### South Africa has ~3m patients on TLD

- Steady increase seen over the year, with estimates of TLD:TEE at approximately 66:34
- Messaging from NDoH has attempted to support the transition
  - Confirmation of ample stock cover for TLD
  - Letter from HIV Programme supporting accelerated transition
  - Dolutegravir based treatment now accessible by all women
  - 2<sup>nd</sup> line patient transition also encouraged
- DTG50 demand has increased recently and is being monitored to assess uptake



CCMDD: Tenofovir & Lamivudine & Dolutegravir (TLD) - Patient Registration or Transition Standard Operating Procedure

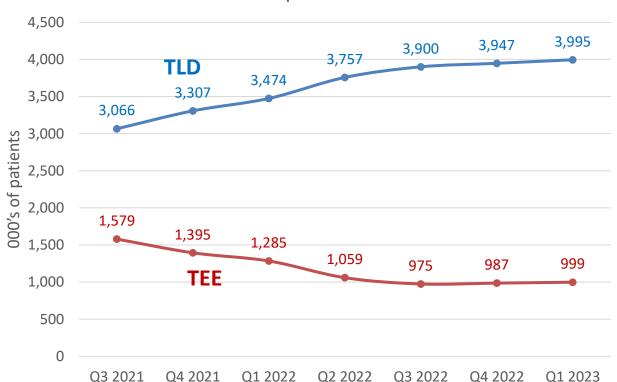






### Adults on main 1<sup>st</sup> line ARTs; 80:20 will not be reached in 2021





#### TLD and TEE patient estimates

Source: Team analysis; TEE/TLD profile based on TROA reaching 6m in Mar-22



2030 NDP



	Patient estimate	Comment				
AZT/3TC+LPV/r	~280,000	_PV/r volumes expected to reduce, but pased on clinician adherence to				
AZT/3TC+DTG	~50,000	communication from HIV Programme on 2 <sup>nd</sup> line patient transition to DTG 50				
AZT/3TC+ATV/r	~10,000					
TDF/FTC+LPV/r	~6,000	Stable volumes expected				
TDF/FTC+ATV/r	~250					
Total	~320,000					







	Patient estimate	Comment				
ABC/3TC+EFV	~90,000					
ABC/3TC+LPV/r	~45,000	Expectation that EFV & LPV/r will be replaced by DTG 50				
ABC/3TC+DTG	~2,000					
AZT/3TC+NVP	~6,000	Stable volumes expected				
ABC/3TC+ATV+r	~3,000	ATV/r combination available but not on contract in current tender				
Total	~160,000					





#### Conclusion



- Tender evaluation underway
- South Africa will continue to have a demand for TEE600
- Transition of 2<sup>nd</sup> line patients does carry uncertainty
- We hope 2022 will be a better year for all but plan for surprises

Looking forward to a successful tender outcome, with stronger relationships and continued innovation for the benefit of our patients







### **THANK YOU**





THE GLOBAL FUND	• • •	• • • •		· · ·	· · ·	• • •	• •	• •	
					· · ·				
ARV Large Global Fur	e <mark>.</mark> Buy	ers ar	nd Sel	lers F	orum	2021	1	• •	• •
	• • •	a a a	· · ·					• •	• •
<mark>- 13-14 Oct</mark> ober 202	1•••	· · ·	• • •		• •	• • •		• •	• •
	••••	• • •	•••	• • •	• •	•••	• •	• •	• •
• • • • • • • • • • •									•••
• • • • •	• • •	• • •	• • •	• • •	• •	• • •	• •	• •	• •

### Key contacts here today



**Cathal Meere** Manager, Pharmaceuticals Strategic Sourcing



**Chirag Rajpuria** Associate Specialist, Principal Recipient Services



**Uranchimeg Badarch** Category Lead, ARVs Strategic Sourcing

# The Global Fund supports countries to fight HIV, TB & Malaria, & mitigate COVID 19 impact

#### \$4.2 billion spend in 2020, 105 countries and 14 multi-country programs

#### HIV in 2020:

- 21.9 million people on antiretroviral therapy for HIV. Coverage increased from 48% in 2015 to 73% in 2020. Global target: 95% by 2025.
- 104 million HIV tests taken; HIV-positive people with knowledge of their status increased from 69% in 2015 to 84% in 2020. Global target: 95% by 2025
- People living with HIV with suppressed viral load increased 41% in 2015 to 66% in 2020. Global target: 95% by 2025.
- 686,000 HIV-positive mothers received medicine to keep them alive and prevent transmitting HIV to their babies in 2020; coverage increased from 44% in 2010 to 85% in 2020. Global target: 100% by 2025.

#### Malaria in 2020:

- 188 million mosquito nets were distributed
- 11.5 million pregnant women received preventative therapy, 135 million cases of malaria treated
- 248 million suspected cases tested for malaria.

#### <u>TB in 2020:</u>

- 4.7 million people received lifesaving treatment for TB in 2020.
- GF provides 77% of all international financing for TB by June 2021 and invested 7.8B USD in TB programs.
- 30% of the GF TB investments support interventions on TB care and prevention, particularly for children and other vulnerable groups such as people living with HIV; 271,000 HIV positive TB patients were on ART during TB treatment in 2020



#### Covid Tx Products

Covid-19 Response Mechanism (C19RM) provided US\$4 billion to date for 107 countries and 16 multi-country programs on protective equipment (PPE), diagnostic tests, and therapeutics (including medical oxygen), to support country responses to Covid-19

#### $m {\mathfrak S}$ THE GLOBAL FUND

## Key ARV achievements in 2021

#### Supply Continuity:

- Continue to drive value through strategic sourcing, H1 2021 ARVs spend alone 400mUSD.
- Price reductions for 1st line regimen by 9% in 2021 compared to 2020 (27% reduction since implementation of the FA 2018-2021)



#### Demand Forecasting:

- Continued improvement of demand forecasting: COVID -19 acted as function for the GF to help shape demand, mandating the PRs to place annual orders by Jun 2021. All forecasted orders have been placed for 2021
- Number of Rapid Supply Mechanism (RSM) orders went down significantly from 21 ARV orders in 2020 to zero orders as of Sep end 2021.



#### **Continues Partner collaboration**

• Continued close working relationship with our key partners including PAHO, UNITAID, CHAI & USAID/PEPFAR\



#### Innovation:

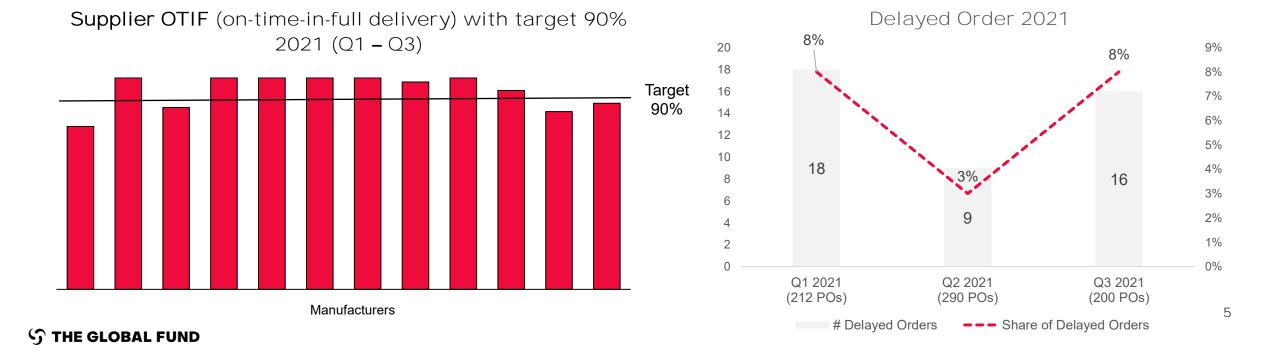
- Supporting efforts to stimulate innovation; accelerate the adoption of new and/or cost-effective products & introduction of better formulations for children-dispersible tabs (DTG 10mg)
- Supply carton-less products -96% of the 1st line ARVs supplied as of Q3 2021.

#### **今 THE GLOBAL FUND**

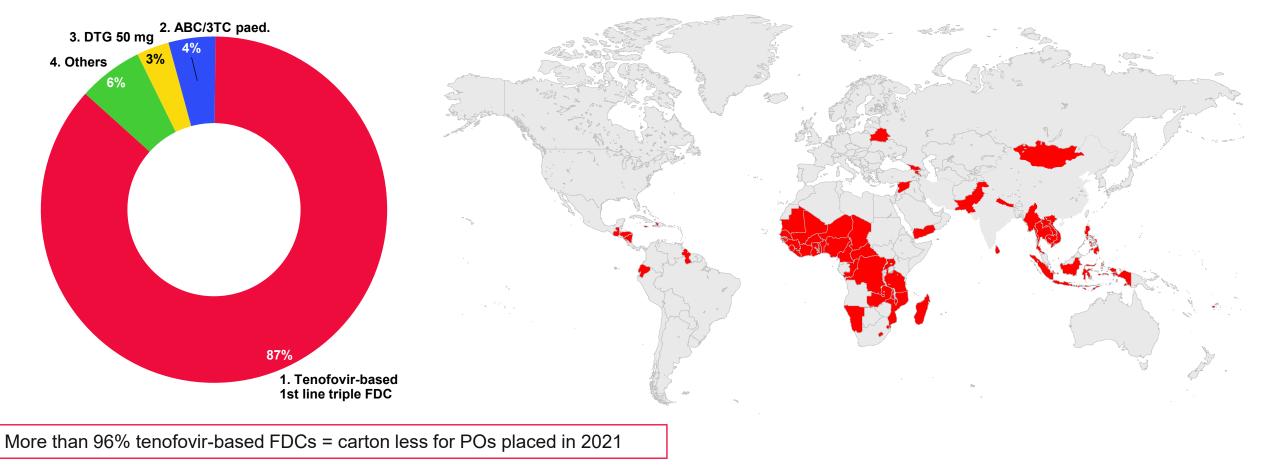
## 2021 supplier performance at the end of Q3

TGF ARV Strategy includes active supplier performance management with a greater focus on

- Supply security
- OTIF (on-time-in-full delivery) Target of 90%
- Shorter lead-times
- Shelf-life extension
- Vendor Managed Inventory (VMI) stock visibility for low volume products, mitigate risk of stock-outs



# 75 million monthly ARV\* packs estimated for 2022 delivery through GF Pooled Procurement Mechanism



\*more detailed forecast for 2022 will be published in November 2021

Armenia, Belarus, Benin, Bhutan, Burkina Faso, Cambodia, Cote d'Ivoire, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo DRC, Ecuador, Gambia, Georgia, Ghana, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Indonesia, Jamaica, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan, Philippines, Sao Tome and Principe, Senegal, Sierra Leone, Sri Lanka, Syrian Arab Republic, Eswatini, Tanzania, Thailand, Timor-Leste, Togo, Uganda, Vietnam, Yemen, Zambia

## Looking Ahead: 2022 Global Fund focus areas



#### Supply continuity:

- Ensuring continued supply & long-term sustainability for strategic medicines and medicines for HIV program
- More focus on upstream supply visibility, support new entrants, diversify supplier base
- Accelerate transition to more optimal health products, smoothen new product uptake



#### Facilitate collaboration:

• Between key partners & suppliers to balance supply & demand, drive stronger health product management across all procurement channels with end-to-end integrated tools and improved demand forecasting



#### Leverage supply synergies:

• Combined tender for ARV, anti-malaria medicines and other strategic medicines in 2022

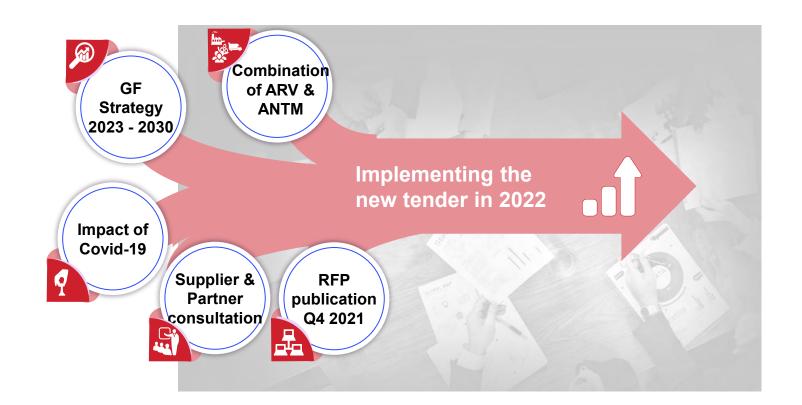


#### Innovation:

- Continue supporting efforts to stimulate innovation
- Accelerate the adoption of new and/or cost-effective products,
- Adequate preparation and planning to respond to new product
- · Reduce environmental footprint and improve traceability
- Supply of 2nd line ARVs with no carton (reduce packaging and shipping cost), implementation of the GS 1 barcoding (improve tracking of products and quality incidents throughout supply chain)

## Global Fund Combined Pharmaceutical Tender

- New tender will combine both ARV's and ANTM categories
- Initial tender timing postponed due to COVID
   19 impact on global supply network
- Supplier and partner consultation completed in Q1-Q2 2021
- New tender implementation in 2022



More information: https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/

#### Check who is updating the website



## Sourcing & Management of Health Products

Overview

Updates

Market Shaping Strategy

**Procurement Tools** 

Health Product Procurement A

Antimalarial Medicines

Antiretrovirals

## Antiretrovirals

Lifesaving antiretroviral medicines (ARVs) are vital for HIV programs and account for nearly 40% of the Global Fund's Pooled Procurement Mechanism annual spend. Our Market Shaping Strategy and our position as one of the largest global buyers of ARVs guide our commitment to facilitating healthy, balanced and sustainable markets.

#### 4.6 million

people receiving ARV treatment procured through the pooled procurement mechanism in 2019

# Thank You



The Global Fund to Fight AIDS, Tuberculosis and Malaria +41 58 791 1700 theglobalfund.org



## PAHO Strategic Fund

Supporting Countries in Improving Access and Availability to Essential Public Health Supplies



#### Vision

Improve the health and well-being of peoples and contribute to the advancement of universal health in the Americas, by strengthening health systems and improving the equitable access to safe, efficacious, and quality medicines and other priority public health supplies.

> Values Solidarity, quality, transparency, equity, efficiency, Pan-Americanism.



#### Mission

Develop a regional platform for PAHO Member States that facilitates collective action to improve the affordability, availability and quality of strategic health supplies in the Americas.

## Platform for Value Creation for Countries & Suppliers





Since July 2015, PAHO has been leveraging Global Fund long term agreements (LTAs) for procuring the majority of the ARVs purchased through the Strategic Fund

- ✓ Vendor performance
- ✓ Supply assurance of products with low volume
- ✓ Access to products allocated to the Global Fund for emergency requests
- Best value for money

- ✓ Maximize use of LTAs: framework agreements
- Increase ARV demand visibility to secure availability
- ✓ Transition/adoption of new products: market intelligence

- ✓ Contract Supplier
   Management
- Harmonize Quality
   Standards & Quality
   Assurance
- Transparency in tendering process (eligibility, technical proposal & evaluation process)

#### ✓ Stay tuned - New joint tender scheduled in 2022 !!!

## Access to ARVs through PAHO SF



UND

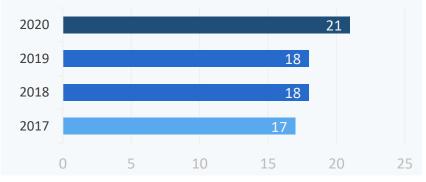
S The Global Fund

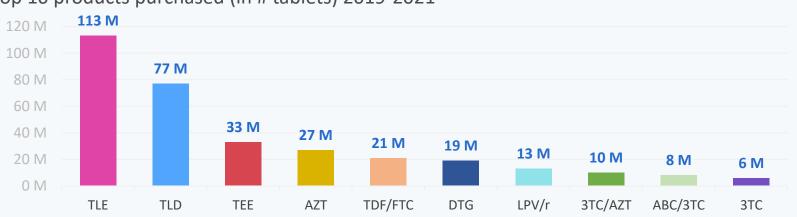


Countries purchasing ARVs through the Strategic Fund

\*between 2017/2020

#### # Countries purchasing ARVs

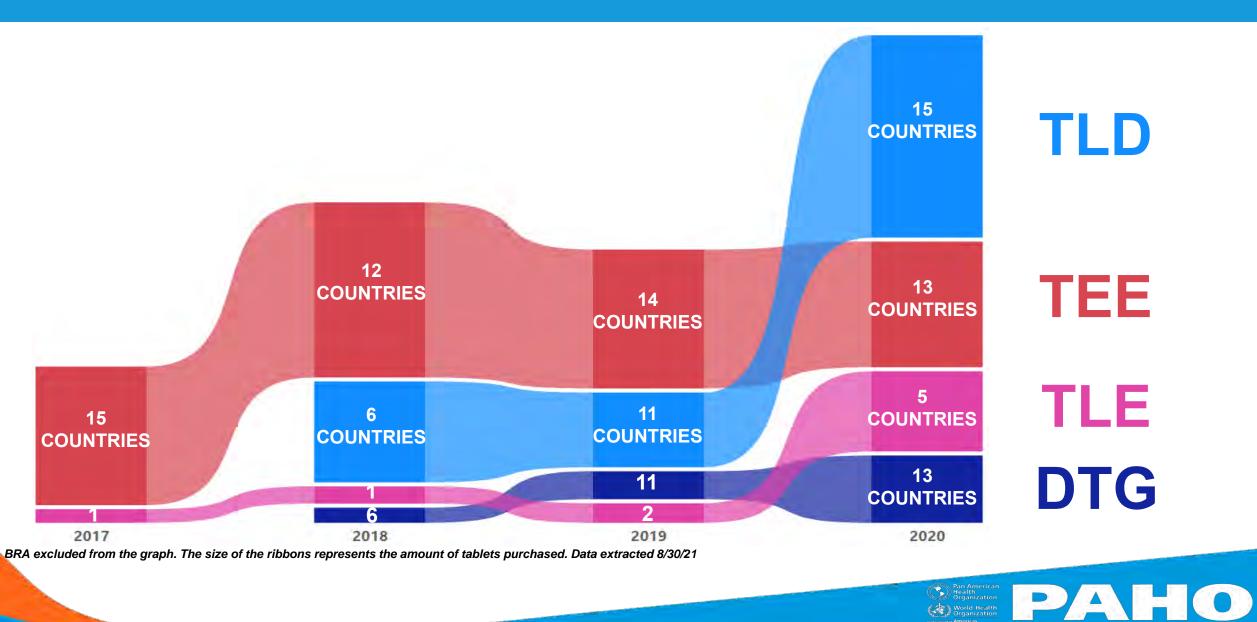




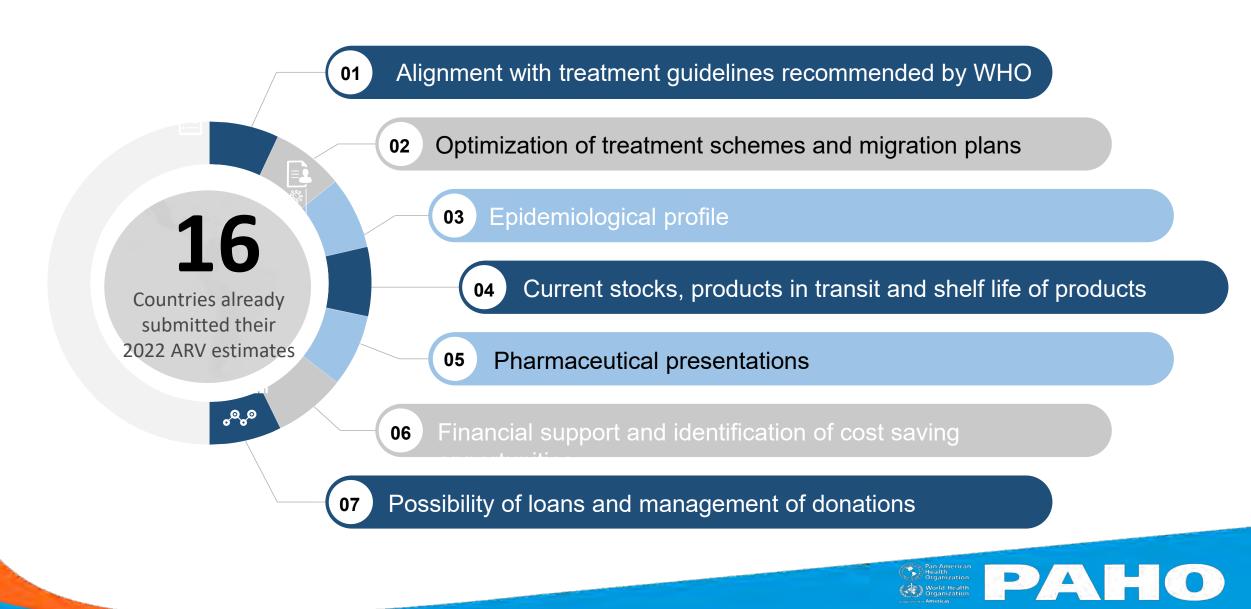
Top 10 products purchased (in # tablets) 2019-2021

World Health Organization World Health Organization Mericas

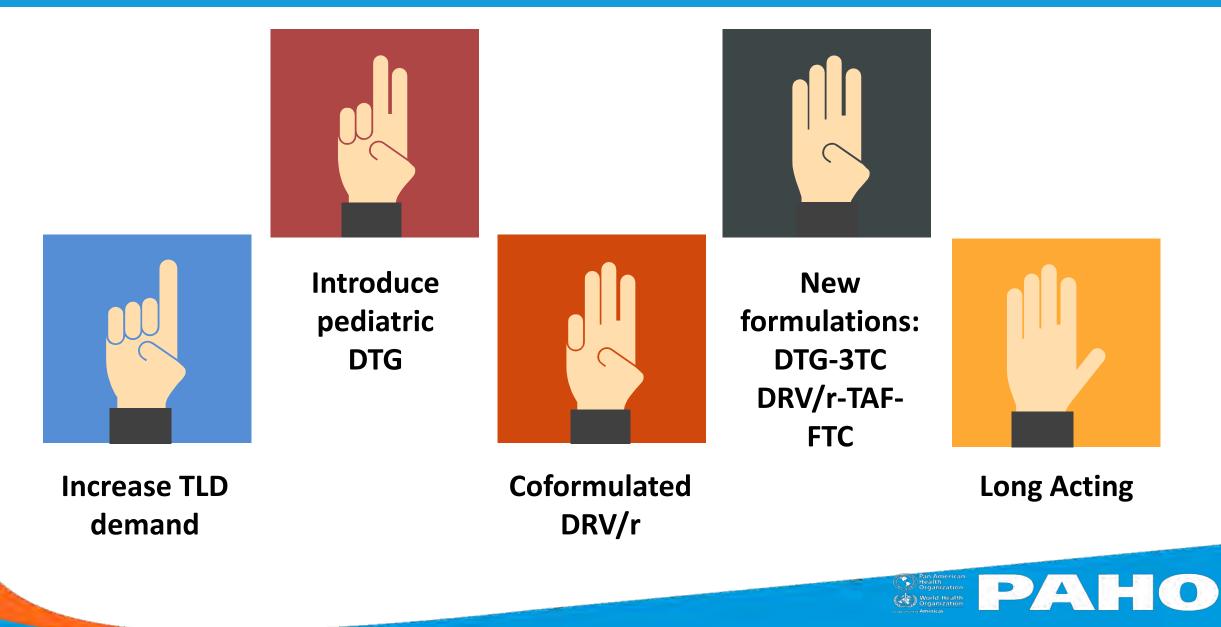
#### Optimization of treatment schemes for Member States



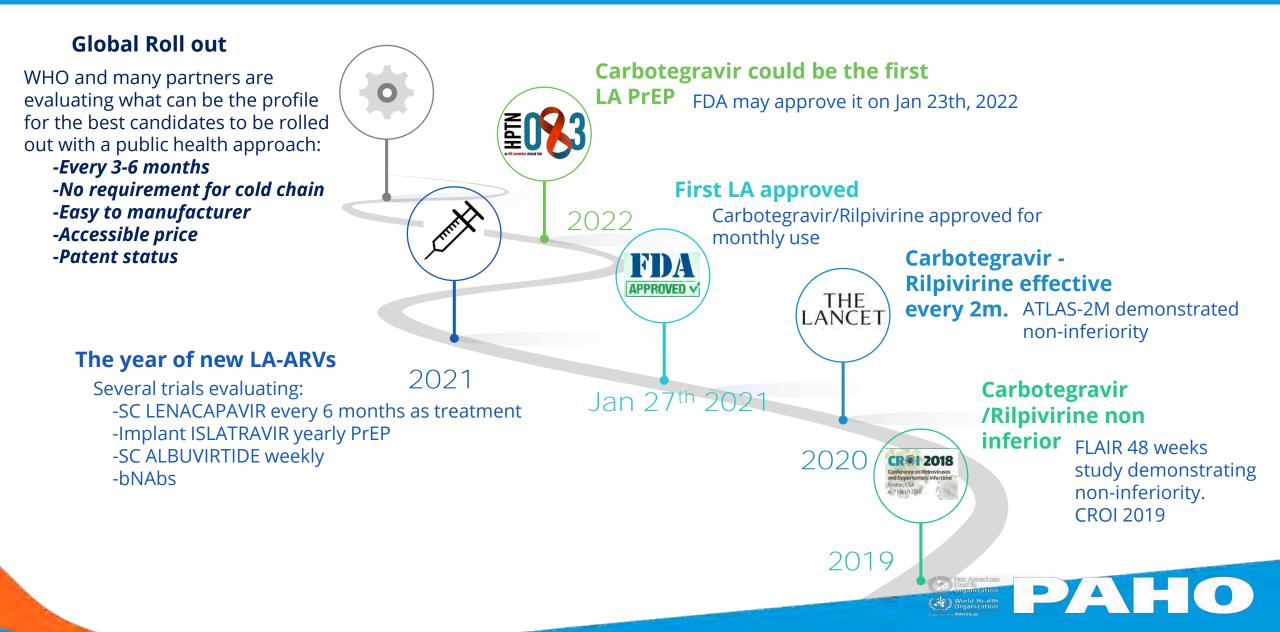
## Regional Demand of ARVs 2022/23



## PAHO ARVs focus for 2022-25



## Long Acting Drugs: the new paradigm for HIV



## The patents will limit the introduction of new drugs

Country	DTG	TAF	Cabotegravir	
Antigua and Barbuda				
Argentina		Opposition	Х	
Bahamas		Х		
Barbados				
Belize				
Bolivia		MPP License		
Brazil	Х	Х	Х	
Chile		Х	Х	
Colombia	Х	Х	Х	
Costa Rica		Х		
Cuba				
Dominica				
Dominican Republic	Х	Х	Х	
Ecuador	Х	Х		
El Salvador		Х	Х	
Guatemala				
Guyana		Х		
Haiti				
Honduras				
Jamaica		Х		
Mexico	Х	Х	Х	
Nicaragua				
Panama		Х	Х	
Paraguay		Х		
Peru	Х	Х	Х	
Saint Lucia		Х		
Suriname				
Trinidad and Tobago	Х		Х	
Uruguay		Х		
Venezuela		Х	Х	
Patent Granted or filed				
No Patent Granted or Filed				
Source: Medicines Patent Pool database and World Intellectual Property (WIPO)				

Currently over 2.1M people living with HIV in LAC Region – and potentially 2M will be affected by the patent protection of new drugs.

<u>ŮŮŮŮŮŮŮŮŮŮŮŮ</u>UU

ιμάματα άτα άτα άτα τα τα

## Establishing supplier partnerships





Going to the next level ....



- ✓ Open communications
- Transparency and responsiveness
- Innovation and development of new products

VISIBILITY & RISK

- ✓ Demand & Supply Visibility
- Production visibility
- Performance management
- Risk mitigation and Impact

 Understanding the region - Pan-Americanism

**ADVOCATE** 

- Expand access agreements in LAC
- ✓ Ensure compliance with regulatory requirements



## THANK YOU!

www.paho.org

PAHOWHO

#HealthForAll #MentalHealth #GetVax #pahowho #BeatNCDs #UniversalHealth

Pan American Health Organization World Health Organization

Healthier together.



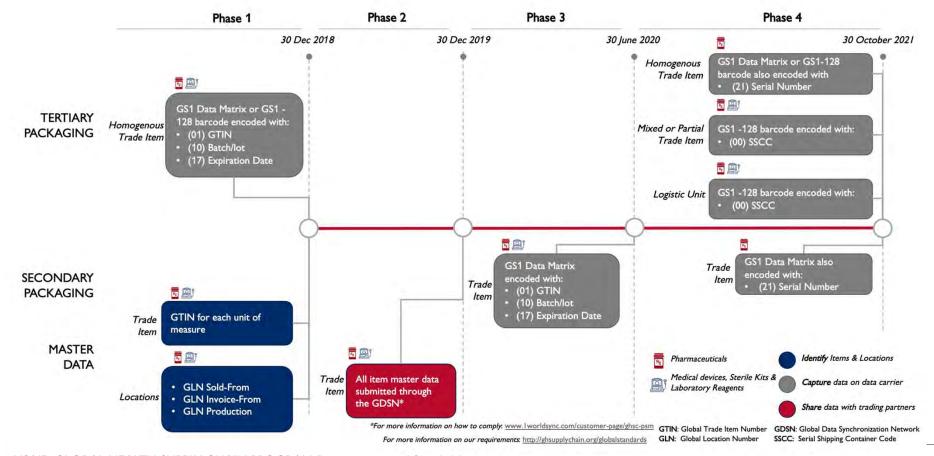
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM Procurement and Supply Management

## Leveraging GSI Standards to Enhance Product Master Data Management

Rachel Smith, Global Standards Technical Specialist

September 2021

#### GHSC-PSM ARV Global Standards Requirements Phased Timeline



USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM-Procurement and Supply Management



### **GDSN Master Data Exchange**

## What master data does GHSC-PSM collect?

- **General item information:** identifiers, brand name, product type
- Product description
- Unit indicators: base, consumer, ordering, dispatch unit indicators
- Dimensions and weights
- **Contact/role information:** brand owner, information provider, manufacturer
- **Pharmaceutical information:** dosage form, controlled substance, route of administration
- **Hierarchy:** parent/child items and quantities
- Storage, handling, and shelf life
- Classifications: GPC, INN, UNSPSC
- Market authorization: Permit numbers and dates

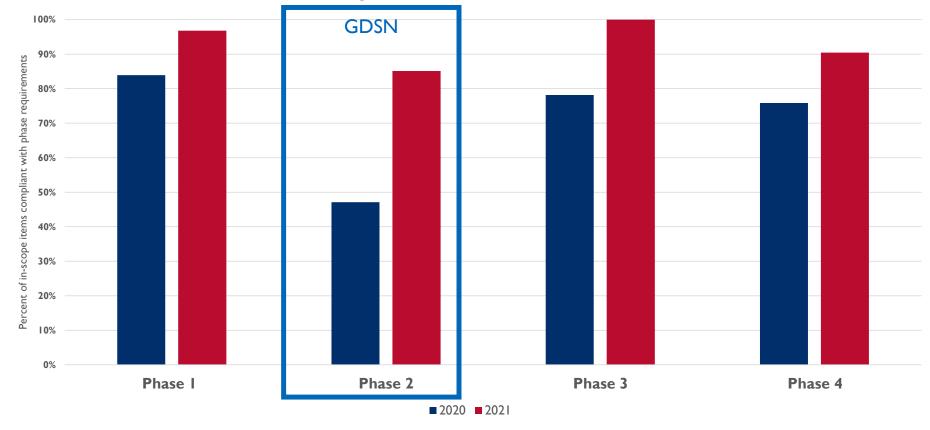
## How GDSN Data is used by GHSC-PSM

GHSC-PSM has adopted and implemented the GDSN to receive item attribute information as the basis of the GHSC-PSM product catalog and seeks the benefits of synchronizing product data with trading partners for both new and existing items

Using the GDSN process aims to improve supply chain data quality and management for you and all of our trading partners.

It will provide USAID-supported countries with the information they need to optimize decision making for GHSC-PSM order planning, procurement, shipping and receiving.

## ARV GHSC-PSM Global Standards Requirement Compliance from October 2020 to September 2021



## Key challenges in receiving complete and accurate product master data via GDSN from ARV suppliers



Key difference between having all product items synchronized in the GDSN and having all required attribute data completed



Continued education of supplier personnel caused by turnover



Specific attribute challenges (e.g. UNSPSC, INN, Market Auth, Route of Admin)



Coordination between synchronization entities

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM-Procurement and Supply Management

## Multiple Educational Resources Available

Global Standards Website: https://www.ghsupplychain.org/index.php/globalstandards

#### Data Synchronization Implementation Guide

• Provides an overview of mandatory, required, and suggested data attributes, GDSN tags, definitions and guidance, and supporting code lists to support compliance with GHSC-PSM GDSN data exchange requirements for suppliers.

#### **GDSN** Webinars

• Currently there are 6 webinars available for GDSN education

#### **GDSN** Attribute Guide

Includes examples for all attributes

#### Learnbite tutorial videos

- How to Interpret CIC Messages
- How to address common attribute challenges
- How I WorldSync can assist suppliers with syncing data with GHSC-PSM?
- How to navigate I WorldSync's GDSN portal

All of these

resources can be found on

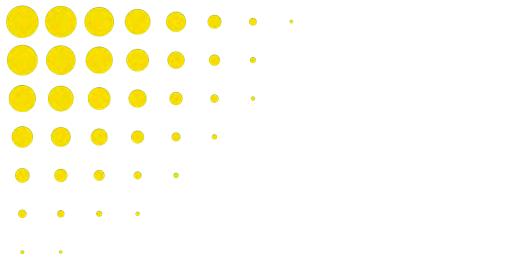
our website!

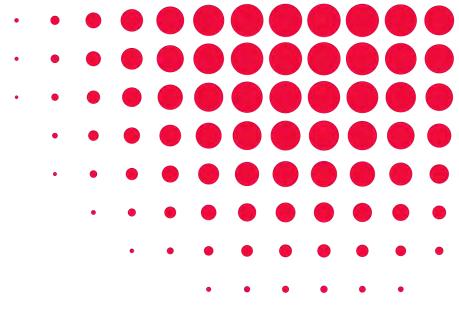


## GDSN Integration Value Proposition for the Global Fund

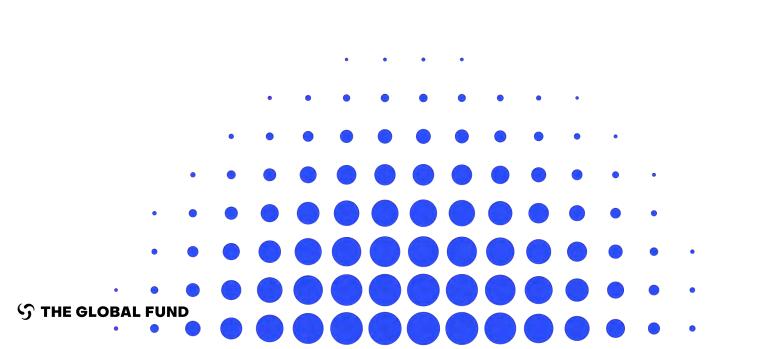
14 October 2021

0

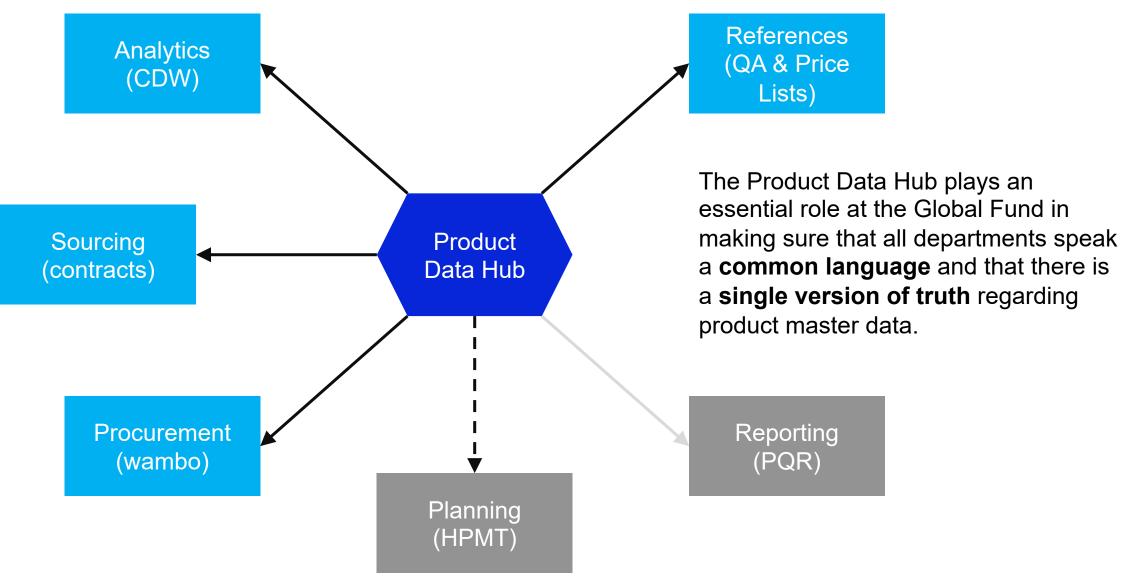




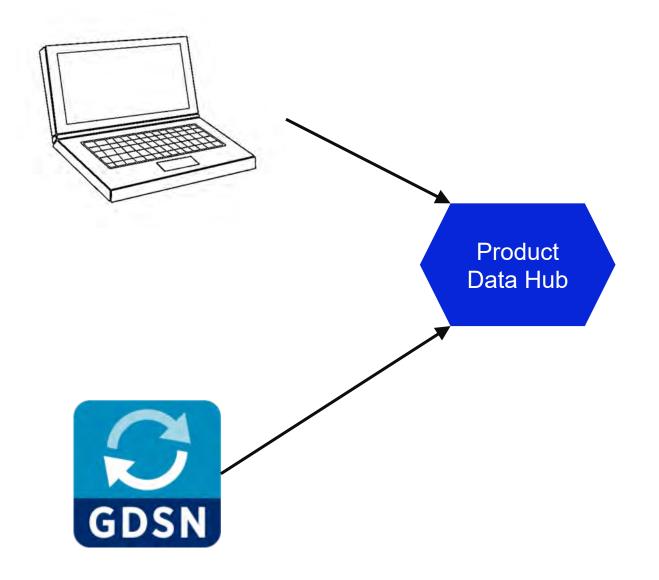
#### 1. Background



#### **Product Data Hub at the center of our infrastructure**



#### **Entering data in the Product Data Hub**



Products and Items are created and entered in the PDH manually with the appropriate workflow. Items will be defined down to GLN/GTIN combinations.

A GDSN Data Pool will be leveraged to enrich items further:

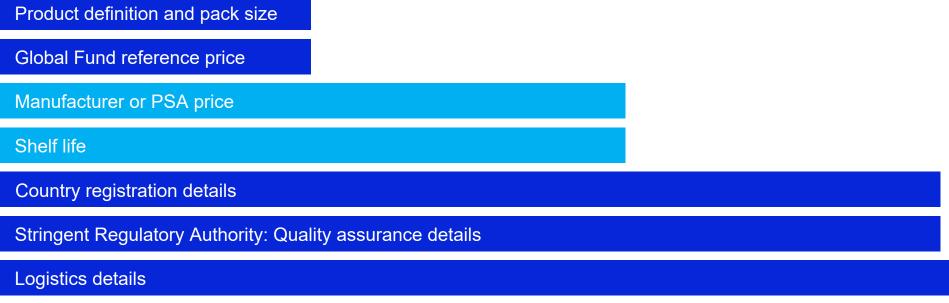
- Volumetrics
- Market Authorizations
- Parent/Child Hierarchy

#### **Product Data Hub data model**

Product	Manufacturer	Manufacturer Site (GLNs)	GTIN
---------	--------------	--------------------------	------

We distinguish the reference Product (**nomenclature item**) from the version produced by a particular Manufacturer (**supplier item**) in a particular production site (**trade item**) with a particular GTIN (**logistics item**).

In the PDH we only created the Nomenclature Item and the Trade Item levels. The Logistics Items are defined as attributes of the Trade Item, which is the target for GDSN Data Pool enrichment.



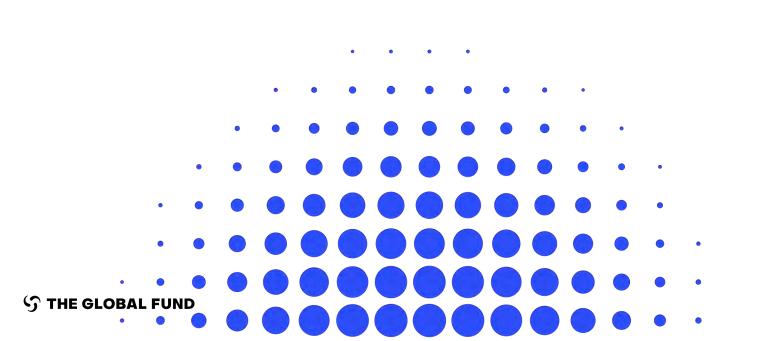
S

GDSN





#### 2. Why GDSN



#### **Immediate value for the Global Fund**

The Global Fund intends to leverage a GDSN Data Pool to receive "faster moving" master data from its manufacturers and stay up-to-date:



Marketing Authorizations are essential for our procurement process: when allocating an order to a manufacturer, Sourcing teams at the Global Fund take into account marketing authorizations in the destination country and **select a compliant manufacturer**. This information is **fast-moving**, and the Global Fund **cannot wait** for new tenders to update its files.

Principal Recipients and Supply Chain partners need information about the Logistics Items (including cases and pallets) in order to plan for proper reception and management of goods. Volumetrics as well as parent/child hierarchies are rarely discussed and captured during tenders. New items for cases will be created throughout the lifecycle of the tender and should be easily captured.

#### **Driving adoption and access to information**

The Global Fund intends to make its master data available to principal recipients and supply chain partners but believes countries should be autonomous in accessing this data.



Leveraging a GDSN Data Pool will force Manufacturers to upload relevant master data and allow Global Fund to monitor its completeness. Country organizations who interface to a GDSN Data Pool will immediately know which fields to request and be assured that the data is there.

# Thank you



The Global Fund to Fight AIDS, Tuberculosis and Malaria

+41 58 791 1700 theglobalfund.org

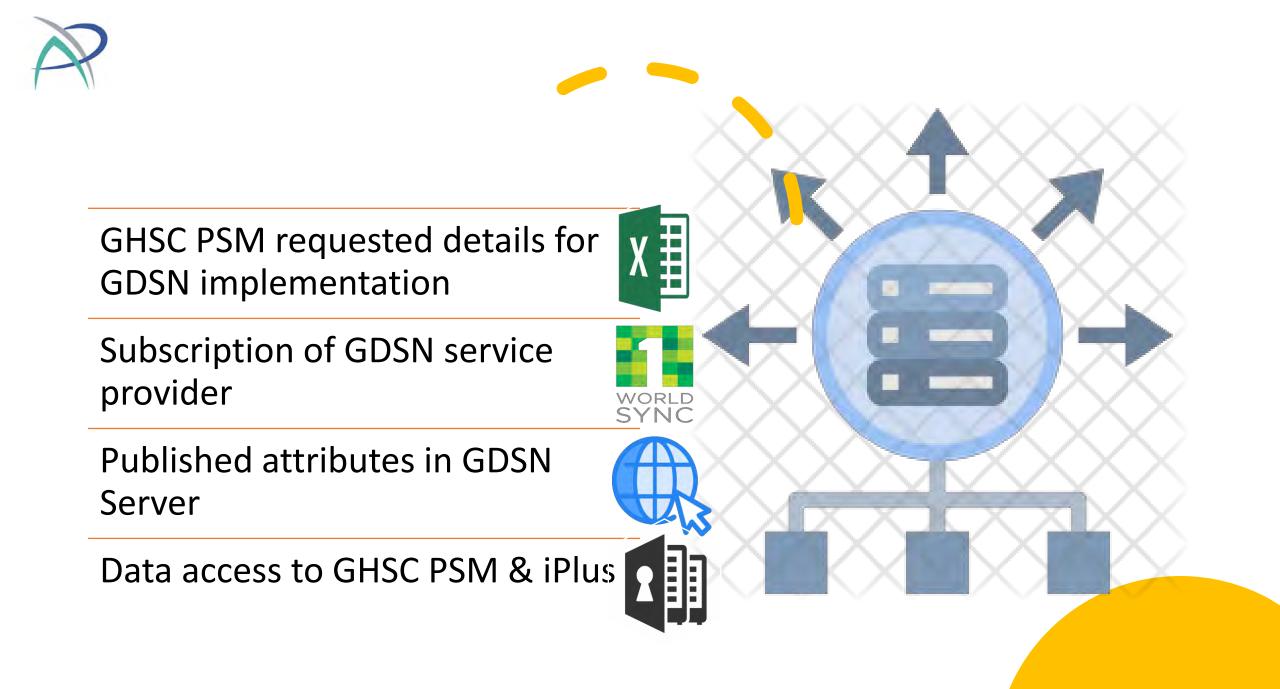
# Global Data Synchronization Network

Presentation by Umesh K - Senior Vice President Global Anti-virals



- Our Journey Implementing GDSN
- Challenges
- Learnings







	SI.No	Challenges	Overcome
	1.	Data collection	Collating & finding right data from various internal department in a phase-by-phase manner.
Challenges	2.	Data entry	Entering the right data for each SKU manually and the data was cross verified twice before the submission.
	3.	New Attributes	Approached 1Ws and GHSC team to learn about the attributes and published in the GDSN server



## Learnings







Knowing All About Product Related Info & New Attributes In Depth Understanding The GDSN Process & Managing Big Data





Avoid Duplication, Accuracy Of Information, Inefficiencies In Manual Data transfer every time can be minimised Real Time Access Of Data Pool By Trade Partners & Buyers

## Thank You

GDSN Service Providers

SI.No	GDSN Service Providers	SI.No	GDSN Service Providers	SI.No	GDSN Service Providers
1	1WorldSync Item management	18	EDICOMDATADP	35	GS1 Mexico - Syncfonia
2	A1Sync	19	EQUADIS SA	36	GS1 Portugal
3	AECOC Data Pool (GS1 Spain)	20	EWAY SYNCWAY	37	GS1 Sweden - Validoo
4	AGENA3000 (PARANGON)	21	GHX Health ConneXion	38	GS1 UK TrueSource
5	Alkemics	22	Global Halal Data Pool / Serunai	39	GS1HUB - GS1 Hungary
6	ANCCNET (GS1 China)	23	Global Product Exchange - Nielsen Brandbank	40	ITN_GDS - ItradeNetwork
7	atrify GmbH	24	GlobeCat - GS1 Croatia	41	Markant Industriewaren-und Vermittlungs AG
8	BC Services - b-synced	25	GS1 Association Greece - Hellasync	42	National Product Catalogue - GS1 Australia
9	Carrefour Group	26	GS1 Canada	43	NECS, Inc.
10	Central Data Bank - GS1 Belgilux	27	GS1 Colombia LOGYCA COLABORA	44	Riversand GDSN Data Pool
11	Comarch EDI MDM	28	GS1 Czech Republic - SYNFONY	45	RIVIR
12	COMMPORT GSDS (CGS) v2.0 R1.1	29	GS1 DAS - Netherlands	46	Salsify Data Pool v1.1.0
13	CONTENTIS AG - GIOLIB	30	GS1 Denmark	47	Systrion AG
14	Datapool atGP	31	GS1 Finland - Synkka	48	TOBBsenkron - GS1 Turkey
15	E2open Global Data Pool	32	GS1 Hong Kong (GS1CN)	49	Viagenie Global Data Gateway
15		33	GS1 Iceland - Gagnalaug		
16	Easy Global Data Pool - Attribytes		GS1 Italy datapool		
17	Edgenet, a Syndigo company				



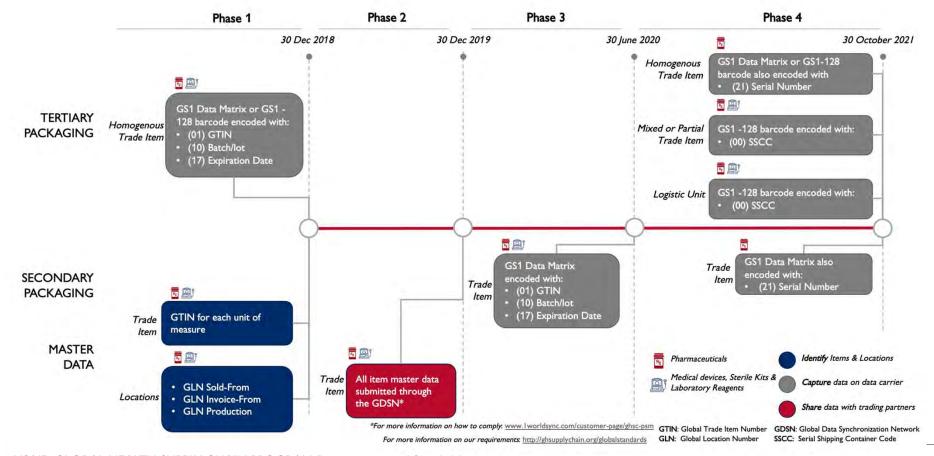
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM Procurement and Supply Management

## Leveraging GSI Standards to Enhance Product Master Data Management

Rachel Smith, Global Standards Technical Specialist

September 2021

### GHSC-PSM ARV Global Standards Requirements Phased Timeline



USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM-Procurement and Supply Management



### **GDSN Master Data Exchange**

## What master data does GHSC-PSM collect?

- **General item information:** identifiers, brand name, product type
- Product description
- Unit indicators: base, consumer, ordering, dispatch unit indicators
- Dimensions and weights
- **Contact/role information:** brand owner, information provider, manufacturer
- **Pharmaceutical information:** dosage form, controlled substance, route of administration
- **Hierarchy:** parent/child items and quantities
- Storage, handling, and shelf life
- Classifications: GPC, INN, UNSPSC
- Market authorization: Permit numbers and dates

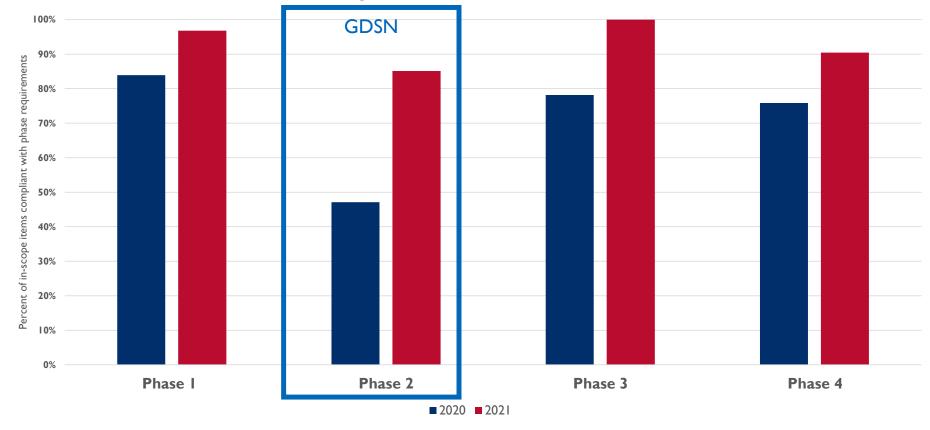
## How GDSN Data is used by GHSC-PSM

GHSC-PSM has adopted and implemented the GDSN to receive item attribute information as the basis of the GHSC-PSM product catalog and seeks the benefits of synchronizing product data with trading partners for both new and existing items

Using the GDSN process aims to improve supply chain data quality and management for you and all of our trading partners.

It will provide USAID-supported countries with the information they need to optimize decision making for GHSC-PSM order planning, procurement, shipping and receiving.

# ARV GHSC-PSM Global Standards Requirement Compliance from October 2020 to September 2021



## Key challenges in receiving complete and accurate product master data via GDSN from ARV suppliers



Key difference between having all product items synchronized in the GDSN and having all required attribute data completed



Continued education of supplier personnel caused by turnover



Specific attribute challenges (e.g. UNSPSC, INN, Market Auth, Route of Admin)



Coordination between synchronization entities

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM-Procurement and Supply Management

## Multiple Educational Resources Available

Global Standards Website: https://www.ghsupplychain.org/index.php/globalstandards

#### Data Synchronization Implementation Guide

• Provides an overview of mandatory, required, and suggested data attributes, GDSN tags, definitions and guidance, and supporting code lists to support compliance with GHSC-PSM GDSN data exchange requirements for suppliers.

### **GDSN** Webinars

• Currently there are 6 webinars available for GDSN education

### **GDSN** Attribute Guide

Includes examples for all attributes

#### Learnbite tutorial videos

- How to Interpret CIC Messages
- How to address common attribute challenges
- How I WorldSync can assist suppliers with syncing data with GHSC-PSM?
- How to navigate I WorldSync's GDSN portal

All of these

resources can be found on

our website!