Global Fund Pharmaceutical Supplier Consultation 2026-2029

March 4th, 2026

Disclaimer

- **The Global Fund Procurement Strategy for the Pharmaceutical Product Category is currently under development and will be finalized following the consultation meeting. The strategy presented is subject to change at the Global Fund's sole discretion.**
- **The data and information contained in this presentation are provided for illustrative purposes only and are based on a limited and preliminary analysis conducted by the Global Fund.**
- **This presentation does not constitute a representation, commitment, undertaking, or assurance of any kind by the Global Fund.**
- **All final information will be set out exclusively in the applicable Request for Proposals (RFP).**

Housekeeping rules

1. **When joining the meeting**, please write your (i) name and (ii) organization in the chat.
2. **The audience will all be on mute.** Only presenters will have access to the microphone & camera while presenting
3. **During the presentations, the chat function will be enabled for questions and comments.** These will be collected and addressed at the Q&A sessions.
4. **The Q&A session is intended for questions and answers from suppliers**
5. **During the Q&A session:**
   i. Please first write your company name followed by your question in the chat.
   ii. You may raise a (virtual) hand if you wish to ask a question verbally.
   iii. Any questions which cannot be addressed in the Q&A session will be answered after the meeting



Meet the Team

THE GLOBAL FUND

Supply Operations



Hui Yang
Head, Supply Operations

Direct Sourcing



Cathal Meere
Manager, Global Sourcing Pharmaceutical



Laurence Delcros
Specialist, Global Sourcing Pharmaceutical



Marlene Coffy
Direct Sourcing
Associate Specialist



Wanlin Ren
Direct Sourcing
Associate Specialist

Ethics Office



Artem Lazurenko
Specialist, Integrity Due Diligence (IDD)

Legal and Governance



Tulin Adiyaman
Principal Legal Counsel



Caroline Middlecote
Senior Manager, Market Shaping, Partnerships and Innovation

Planning & Procurement



Martin Auton
Head of Planning and Procurement



Moses Muputisi
Manager Demand, Supply Planning, and Forecasting

Technical Advice & Partnership (TAP)



Vindi Singh
Senior Disease Advisor, HIV



Htin Kyaw Thu
Senior Specialist, Malaria Case Management

Quality Assurance



David Karenye
Manager, Product& Supplier QA Compliance



Sandrine Cloez
Specialist, Pharmaceutical Products QA

Todays Agenda

	Opening Session		
	1. Opening remarks	10 min	**Hui Yang** / *Head of Supply Operations – Global Fund*
12.00 -12.30	2. Strategy Update & Next Gen Market Shaping	10 min	**Caroline Middlecote** / *Senior Manager Market Shaping, Partnerships & Innovation - Global Fund*
	3. Non-Grant Financed procurement through PPM/Wambo	10 min	**Martin Auton** / *Head of Planning and Procurement – Global Fund*
	Pharma Strategy & Category Insights		
12.30 -13.10	4. Pharma market observations and evolution	10 min	**Cathal Meere** / *Manager Global Sourcing Pharmaceuticals – Global Fund*
	5. Pharma Procurement strategy 2026- 2029	20 min	
	6. Request for Proposal (RFP) approach & Timelines	10 min	**Marlène Coffy /** *Associate Specialist Global Sourcing Pharmaceuticals – Global Fund*
	Quality & Compliance		
13.10 - 13.30	7. Quality Assurance Requirements	10 min	**Sandrine Cloez** / *Specialist Quality assurance Pharmaceuticals products – Global Fund*
	8. Integrity Due diligence	10 min	**Artem Lazurenko** / *Specialist Ethics, Risk Management – Global Fund*
13.30- 13.40	***Break***		
	Disease and Technical update		
	9. TB Update	10 min	**Grania Brigden** / *Senior Advisor TB – Global Fund*
	10. HIV Update	10 min	**Marco Antonio Vitoria** / *Medical Officer, Department for HIV, Tuberculosis, Hepatitis and Sexually Transmitted Infections – WHO*
13.40 - 14.30		10 min	**Vindi Singh** /*Senior Disease Advisor – Global Fund*
	11. ANTM update	10 min	**Andrea Bosman /** *Team Lead, Malaria and NTD Case Management and Chemoprevention – WHO*
		10 min	**Htin Kyaw Thu** / *Senior Specialist Malaria Case Management – Global Fund*
	Partners		
14.30 - 14.40	12. PAHO Presentation	10 min	**Daniel Rodriguez** / *Director Procurement & Supply Management – PAHO*
14.40- 15.30	Q&A / Discussion	50 min	**all**

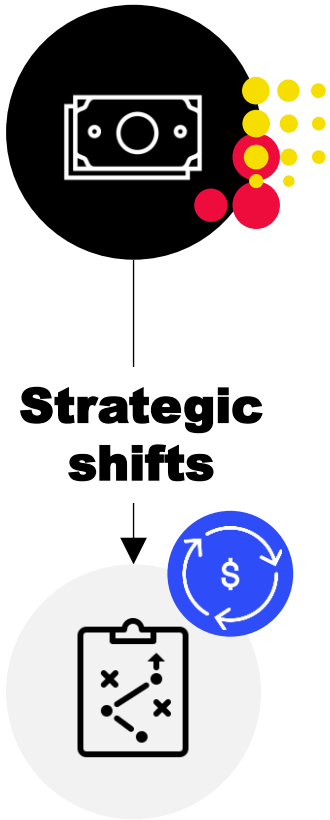
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Opening Remarks

Hui Yang

Head of Supply Operations

The Global Fund's replenishment will enable the continuation of HIV, TB, malaria programs



8th Replenishment: US$12.64 billion total pledge, the Board approved US$10.78 billion in allocations to countries for the 2027–2029 implementation period, complemented by US$260 million for catalytic investments.

To maximize the outcomes for GC8, the Global Fund introduced key strategic shifts to focus resources toward the poorest countries with the heaviest disease burdens and support countries in accelerating on their path to self-reliance as they work toward ending the three diseases.

The strategic shifts will guide countries in the next grant cycle, with:

1. Greater prioritization of the least-resourced and highest-burden countries.
2. Defined, predictable transition timelines tailored to national contexts, disease burden and economic conditions.
3. Optimized use of all available resources through rigorous programmatic prioritization, increased co-financing, market shaping, reinforced integration into national health systems, and community systems financing.

*These catalytic investments are designed to accelerate progress in priority areas, such as expanding access to innovative health products through market shaping and strengthening regional manufacturing capacities, thereby amplifying the impact of country grants. An additional US$306 million in private sector funding has been earmarked for catalytic investments. Private sector resource mobilization efforts are ongoing and are expected to further increase the total funding available for catalytic investments.

Key Messages

1. **The Global Fund remains a stable, predictable, and long-term partner for the pharmaceutical industry.**
   Our pooled procurement mechanism, reliable demand consolidation, and disciplined performance management continue to provide manufacturers with strong visibility and market stability.

2. **Access to affordable and quality assured health products and innovation remain strategic priorities.**
   The Global Fund will deploy targeted market-shaping tools, including special contracting terms, innovation windows, and deliberate supplier-base expansion, to accelerate the introduction of new products and strengthen competition in close alignment with the upcoming tender roll-out.

3. **Strengthening supply resilience—including regional manufacturing—will be central in the 2027–2029 tender cycle.**
   We will promote multi-sourcing, supply security, and expand allocation to qualified Africa-based manufacturing to mitigate global shocks and ensure uninterrupted access for countries

4. **Maintaining full Quality Assurance compliance is non-negotiable and foundational to participation.**
   Only products and manufacturing sites meeting the Global Fund QA Policy, WHO PQ, SRA/WLA, or ERP eligibility will be procured—ensuring patient safety and consistent supply.

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Strategy Update & Next Gen Market Shaping

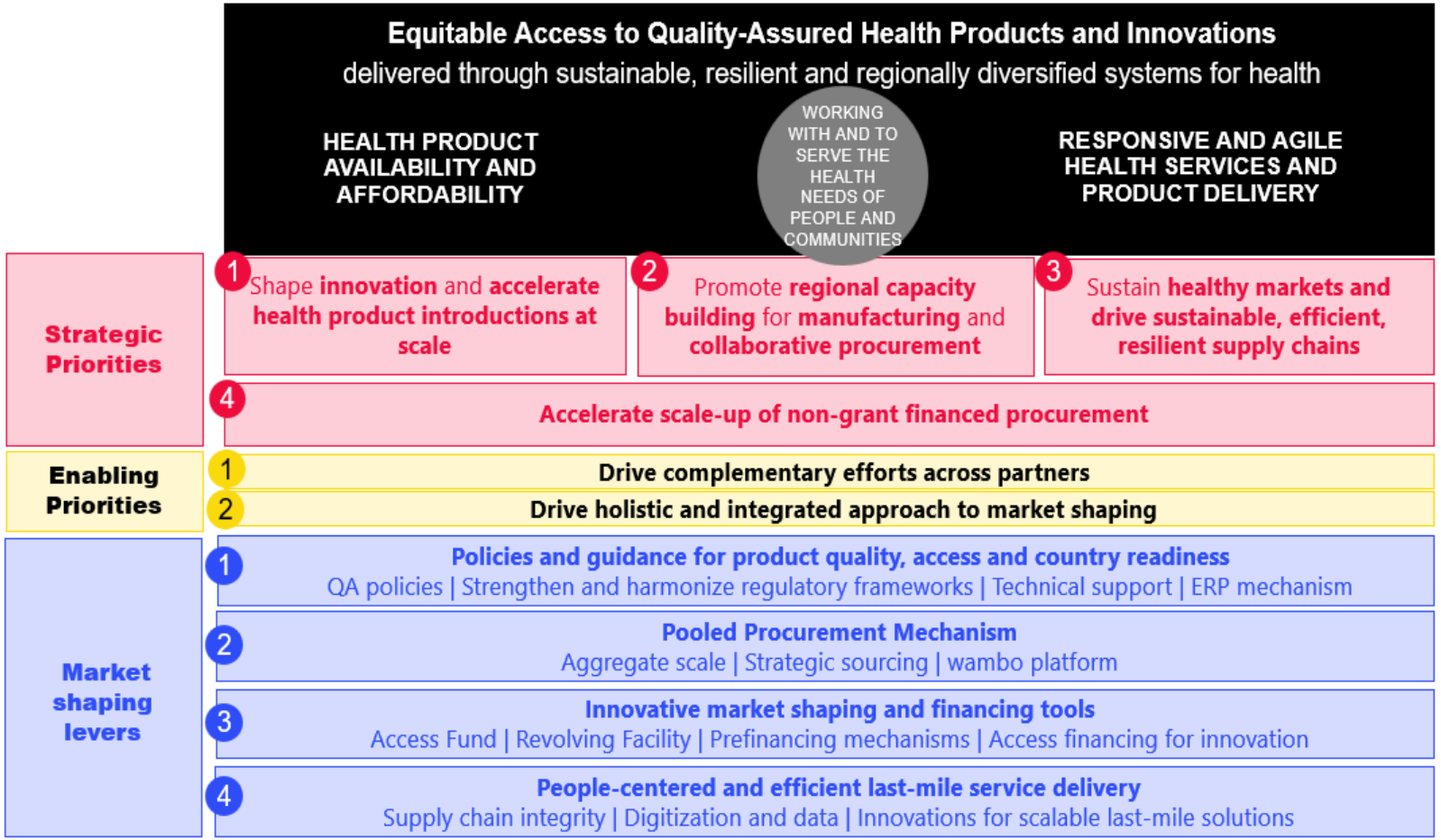
Caroline Middlecote

Senior Manager Market Shaping, Partnerships & Innovation

Global Fund's procurement is a key enabler of achieving our NextGen Market Shaping goals to maximize impact, value for money and sustainability

Key Highlights of NextGen Market Shaping

- Increased focus and importance of sustainability and transition
- Continued focus on accelerating access to innovation needed to end the three diseases, with a pathway to sustainable, affordable access
- Focus on regional capacity building and support for regional manufacturing
- Enabling non-grant procurement through PPM/Wambo to enable continued access to quality assured health products as countries transition



The evolved NGMS framework remains within the scope of the Board-approved GC8 NGMS priority.

To advance on NextGen Market Shaping interventions we need to deepen our collaborations

1. High performing service delivery, supply agility, mitigate stockout risks.
2. Sustained investment in R&D, innovation, and manufacturing capabilities.
3. Enhance quality assurance system and quality controls.
4. Explore opportunities for technology transfer, south-to-south collaboration to support regional supply base diversification.
5. Drive productivity and operation efficiencies.
6. Proactive engagement and communication to ensure responsiveness.
7. Support Global Fund’s approach to scale up the non-grant financed procurement mechanism.

Non-Grant Financed Procurement through PPM / Wambo

Martin Auton

Head of Planning & Procurement

Accelerate and scale up the non-grant financed procurement mechanism to sustain access

As countries need to transition towards domestically funded health responses, the Global Fund intends to scale up its non-grant financed procurement mechanism to support access to quality health products at low cost.

VISION

Enable greater access to life-saving health products across procurers by leveraging Global Fund's PPM/wambo.org as part of the sustainability pathway and in support of country transitions

PROBLEMS WE ARE TRYING TO SOLVE

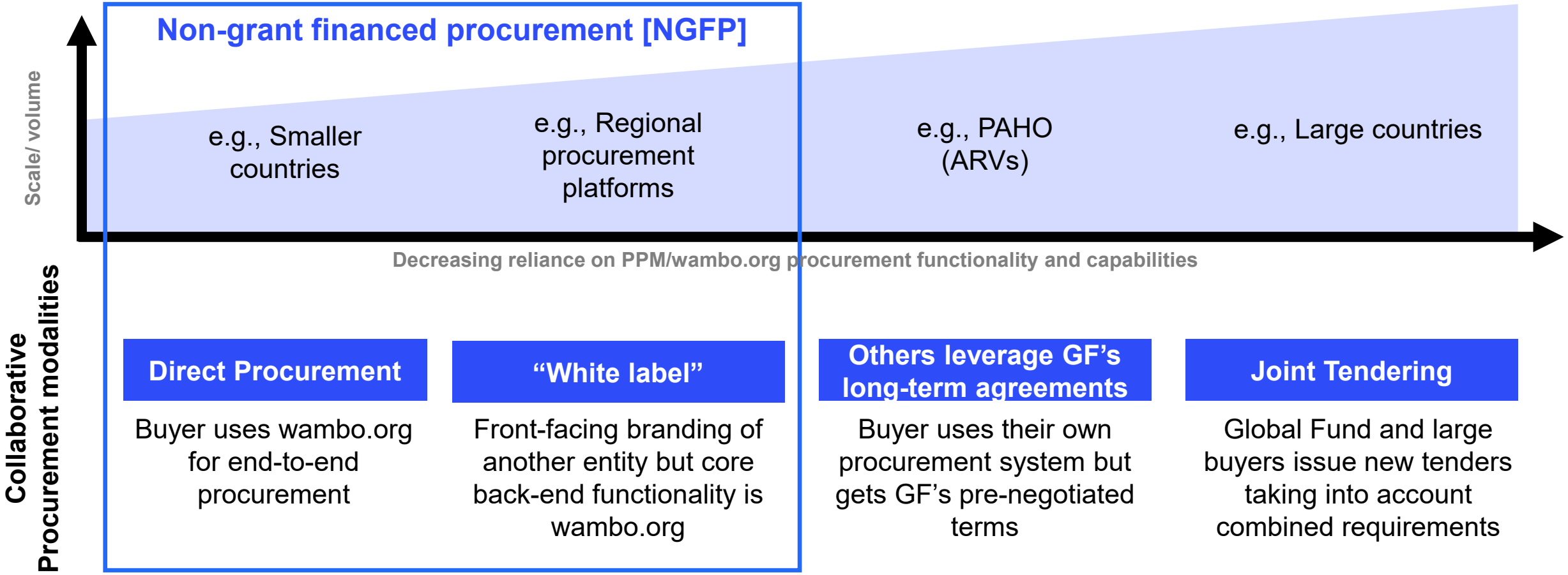
1. **Fragmented / low scale procurement:** Many small buyers negotiating individually with manufacturers means higher product costs, and in some cases delayed/no access to essential medicines
2. **Low cost-efficiency of domestic procurement:** Current domestically financed health product procurement often experiences higher product prices and much higher transaction costs
3. **Variable quality products:** Application of different quality standards may translate to substandard products and compromised program delivery outcomes
4. **Delayed and/or unequal access to innovations:** New innovations often take much longer for individual countries to access without a large, central concerted effort

WHAT WE SEEK TO ACHIEVE

1. **Sustainability/Transition:** More diversified sources of financing for health commodities that sustain scale and facilitate greater national program responsibility
2. **Availability and Affordability:** Continually lower costs while preserving global supply security for essential health products
3. **Quality:** Increasing usage of quality-assured products in country programs with internationally harmonized standards
4. **Innovation:** More rapid adoption of new, game-changing biomedical products through improved market shaping / coordination across buyers

Accelerating the non-Grant financed procurement mechanism as part of the sustainability and transition pathway

Global Fund's Procurement Policy enables different approaches for collaborative procurement with partners/buyers suited to the needs. These differentiated models can help maximum scale synergies and drive cost efficient and transparent procurement at national, regional and global levels



Market Evolution & Observations

Cathal Meere

Manager Pharma Sourcing

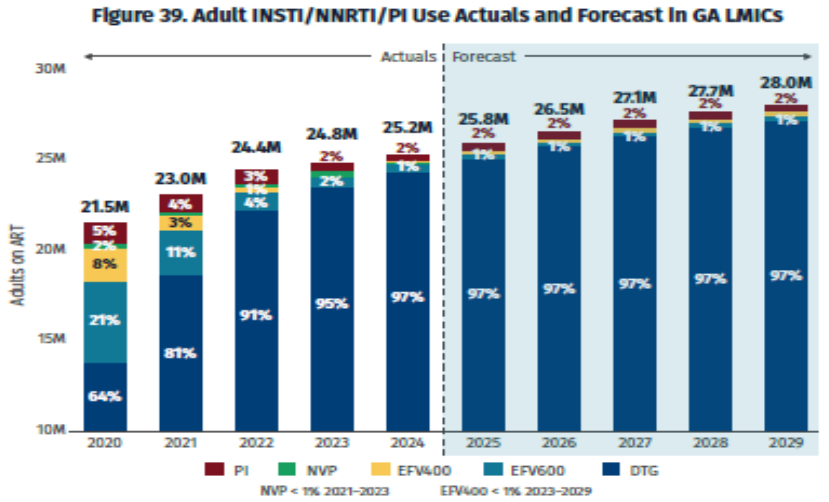
ARV Market

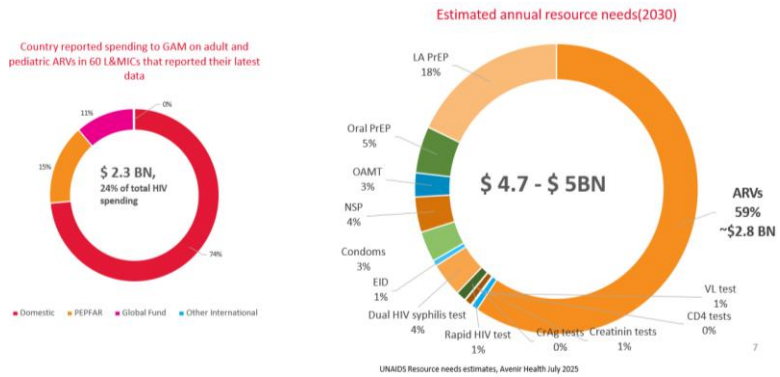
TLD & DTG based regimen: driving HIV treatment through 2029

- **Treatment Dominance:** Treatment is projected to remain the largest HIV spend category through 2030.
- **DTG-based regimens and TLD** driving the majority of volume for both adults and children.
- **Expanded WHO Recommendations:** Inclusion of alternative first-line regimens, such as LD, TAF ED, and TAF LD, is not expected to materially impact overall demand.
- **Innovation Pipeline: A large development pipeline** including Lenacapavir Gx, dual prevention pill, and once-monthly oral PrEP candidates—is emerging and will be key new product introduction in the coming years.

Note:
LD: Lamivudine + Dolutegravir
TAF ED: Tenofovir Alafenamide + Emtricitabine + Dolutegravir
TAF LD: Tenofovir Alafenamide + Lamivudine + Dolutegravir

Forecast 2025 – 2029*





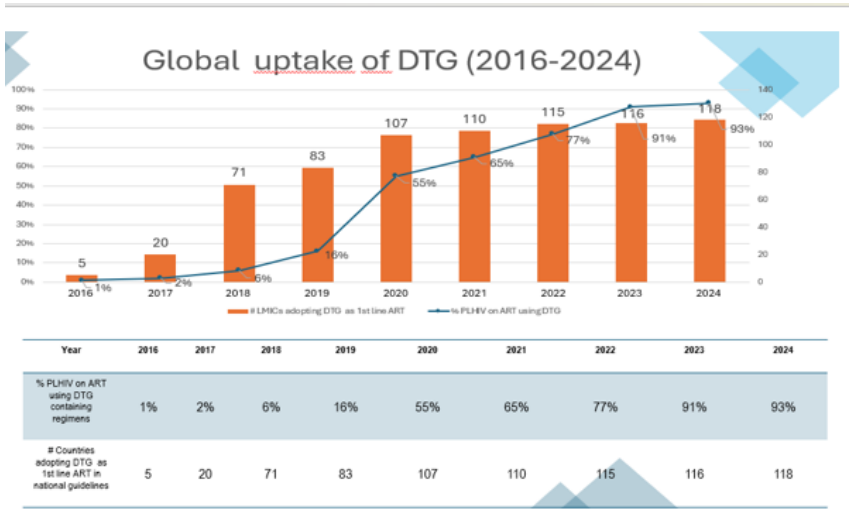
* Source: CHAI, UNAIDS Report 2025

ARV Market Development following 2018 TLD introduction

DTG-Based Treatment Landscape (2018–2025)

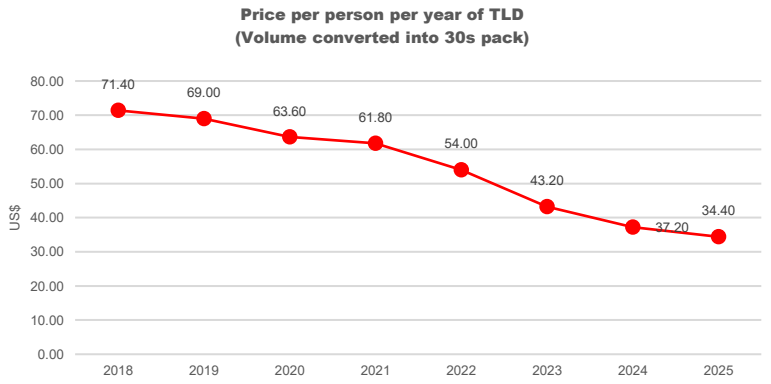
- **Rapid Adoption**: Since TLD's introduction in 2018, DTG-based products now constitute over 90% of the treatment portfolio.
- **Market Support:** Global Fund tenders and partner engagement have helped strengthened manufacturing capacity and created a sustainable supplier base.
- **Cost Reductions:** Manufacturing efficiencies, high volumes, and competition have driven a 52% decrease in TLD pricing from 2018 to 2025.
- **Future Pricing Trends:** Further price reductions are possible, but the rate of decline is expected to slow as non-commercial factors become primary drivers.
- **Supplier Consolidation**: A limited number of suppliers maintain larger ARV portfolios including for low volume transitioning products

Dolutegravir Transition since 2018



Year	2016	2017	2018	2019	2020	2021	2022	2023	2024
% PLHIV on ART using DTG containing regimens	1%	2%	6%	16%	55%	65%	77%	91%	93%
# Countries adopting DTG as 1st line ART in national guidelines	5	20	71	83	107	110	115	116	118

TLD Reference Price

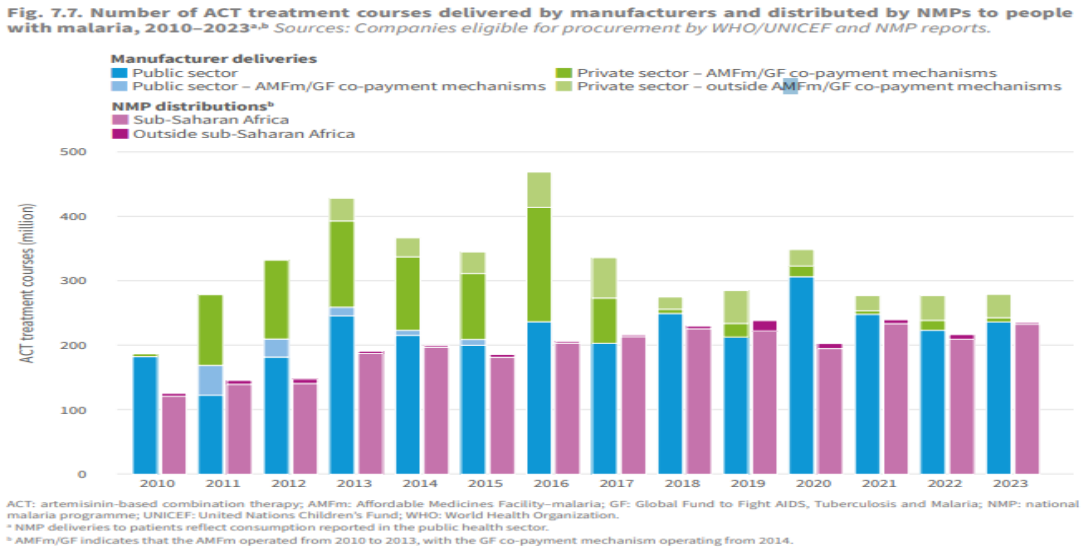


ANTM Market

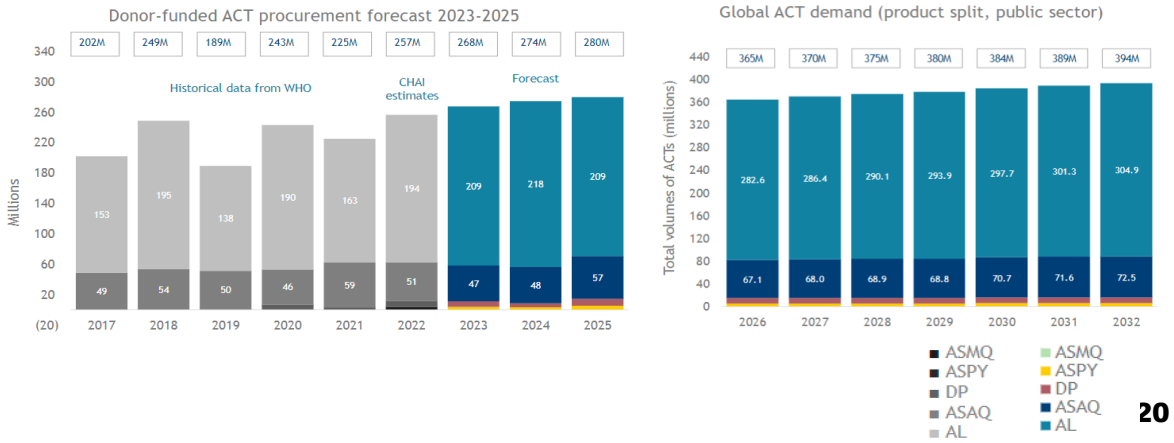
Projected Growth and Trends in the Anti-Malaria Market (2022–2032)

- **The global malaria market is primarily public, accounting for 68% of its USD value,** while the private sector represents 31%.
- **A notable share of the private market remains unquantified** due to informal market drug sales.
- **ANTM Market growth projected to increase** between 2022 and 2032 by an average of **4.4%** annually.
- **AL and ASAQ will continue to be the two most procured ACTs**, accounting for approximately **79%** and **17%**, respectively, of the total ACT procurement.
- **However, use of DHA-PPQ and ASPY will increase from 2024** in response to resistance concerns & supported by market shaping initiatives.

2024 Malaria report* (WHO)



ACT forecast 2023-2032 (CHAI)

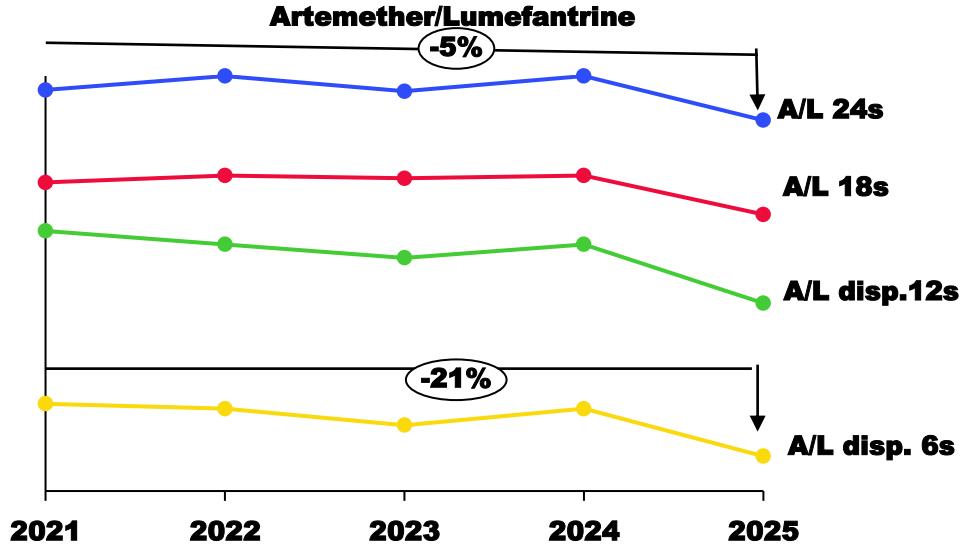


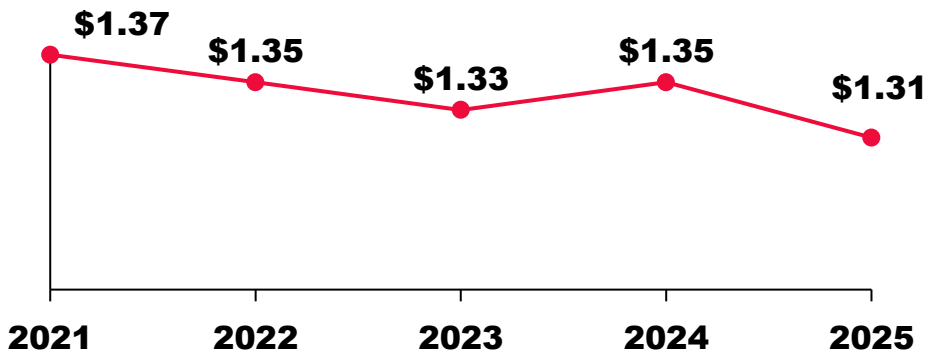
** Source: WHO, UNICEF and NMP & CHAI report*

Roll Back Malaria, Global Malaria Dashboard, Short-term & Long-term Commodities Forecast, endmalaria.org (Note: Underlying forecast data produced by CHAI).

AL and Artesunate Injectables are the main volume drivers in the ANTM portfolio

- **AL and Artesunate injectables drive portfolio volume**, making their pricing and cost dynamics critical to ANTM performance.
- **AL Average Pricing has remained broadly stable** since 2021, with a slight downward trend across most SKUs
- **Artesunate Injectable pricing has also remained stable** however we believe that additional suppliers will support increased competition
- **First line diversification** will impact overall budgeting as ASPY and DP are scaled up to tackle growing resistance
- **API remains the dominant cost driver**, meaning finished dosage form pricing is highly exposed to pricing fluctuations.





Confidential

Market Observations & Supplier Feedback

Cathal Meere

Manager Pharma Sourcing

Global Market Pressures Reshaping Pharma Supply

Why supply security and sustainability matter more than ever:



1. Access to medicines risk is growing
Geopolitical instability, climate shocks, and supplier consolidation are structurally weakening supply resilience, increasing the likelihood of disruptions and shortages in priority markets.

2. Affordability pressures are intensifying
Inflation, currency volatility, rising compliance costs, and higher logistics expenses are eroding purchasing power and threatening the long-term sustainability of affordable pricing models.

3. Financing variability requires adaptable planning

As funding levels and priorities evolve procurement planning must remain flexible to support stable supply and enable sustainable manufacturer investments

Key Message

Global health markets are becoming more fragile, future resilience will depend on stronger supply security & sustainable pricing. Domestic funding will play an increasingly important role in supporting the response

Market Observations – Pharma Sector

The Global Fund has identified several developments within the Pharma sector which directly impact the Pharma strategy.



1. **Market shaping & Innovation must actively guide portfolio transitions** e.g., resistance management and new therapy and prevention tools. Innovation and new product introduction are key to optimal portfolio alignment

2. **TLD continues to anchor first-line ARV demand**, with minimal movement expected toward alternative regimen

3. **ANTM will see a shift in first line treatment** demand driven by growing resistance.

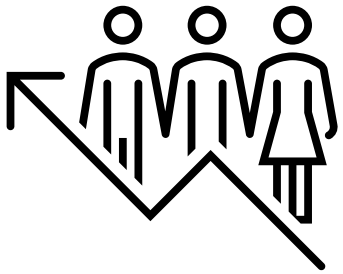
4. **API make or buy decisions remain fundamental** in determining cost competitiveness, supply security and long-term FDF strategies.

Key Message

The pharma market is shifting together with other external factors including new innovations, resistance and pricing pressure, redefining priorities

Partner & Supplier Consultation Feedback

Global Fund Sourcing has consistently gathered feedback from Partner & Supplier consultations to support the strategic direction, building on previous RFP cycles and review meetings



1. **The Global Fund's long-term contracts create market stability**, predictability planning and pricing stability. Together with our partners this is helping to strengthened manufacturing capacity planning and create a sustainable supplier base.

2. **Portfolio optimization and prioritization,** utilizing market-shaping initiatives for key innovations & products, and strengthening supply chains will support manufacturers to plan capacity, improve cost and stabilize supply

3. **Procurement through PPM/wambo including using non-grant funding** (domestic and partner resources) and collaborative procurement arrangements support demand consolidation

Key Message

The Global Fund pharma sourcing strategy has evolved over previous cycles in response to the evolving landscape and reflecting on supplier and partner feedback

Category Insights & Outlook

Cathal Meere

Manager Pharma Sourcing

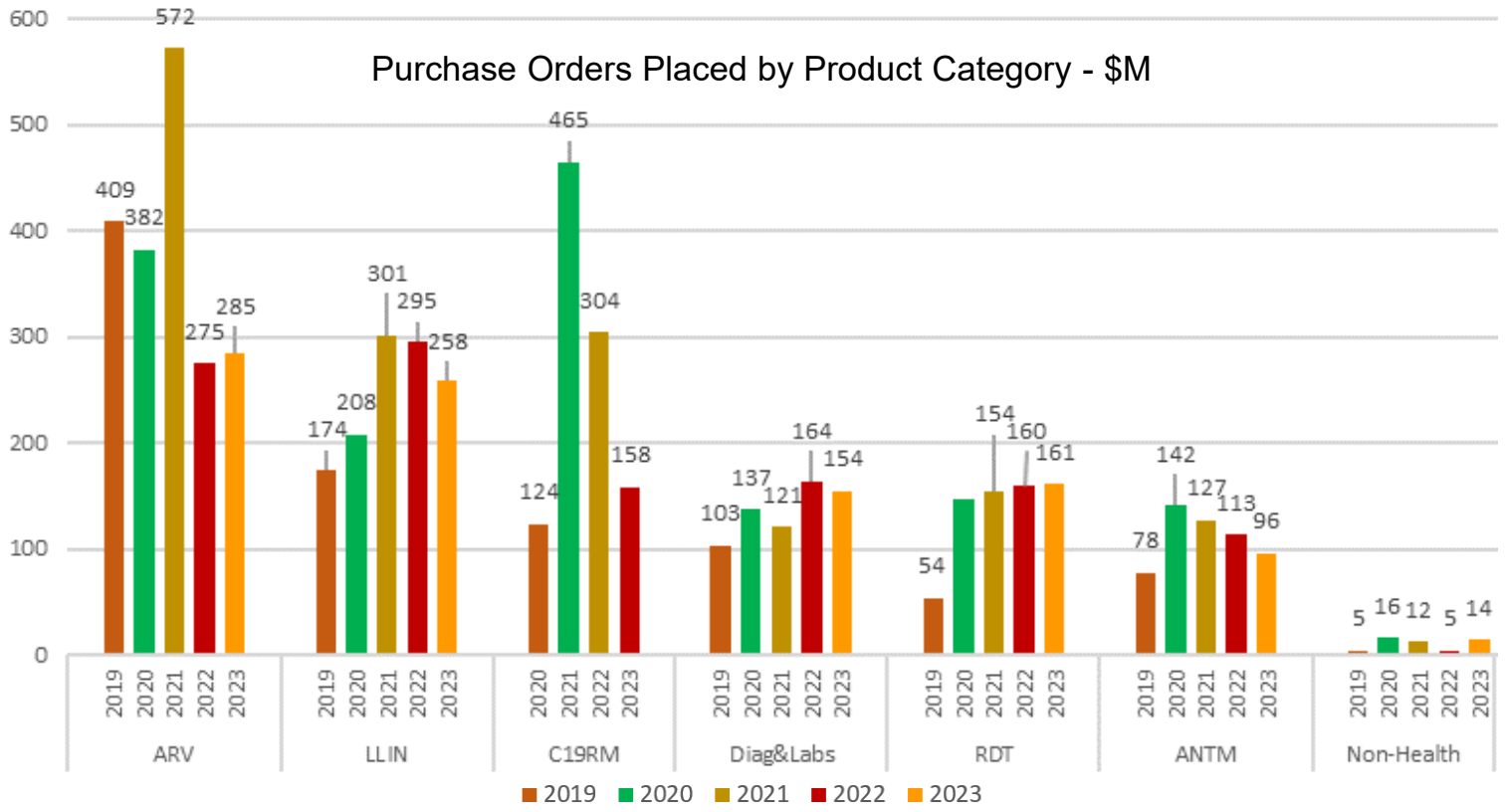
Category volumes consistent over time except for C19 (50% decrease)

- C19RM: Shift from Pandemic Response to Pandemic Preparedness causing lower POs as PO wave 2 took shape
- The main drivers on ANTMs decrease (Sourcing advised to look at the full cycle): product drivers for ANTM and ARV in the annex

2023 vs 2022

▼ 6% Diagnostic & Laboratory	▲ 0,4% Rapid Diagnostic Tests	▲ 209% Non-Health Products*
▲ 4% Antiretrovirals (ARV)	▼ 16% Antimalarials (ANTM)	▼ 95% PPE

	Year	ARV $M	ANTM $M
	2024	294	159
	2025	272	147
2026	(As of July)	288	82



Parameters: Wambo PO Line classification Unutilized Funds Report (UUFR).
Excluded: PSM Costs, Non-Grant Transactions
Report date: 08 Jan 2024

THE GLOBAL FUND **Non-Health Products: increase from $5M in 2022 to $14M in 2023*

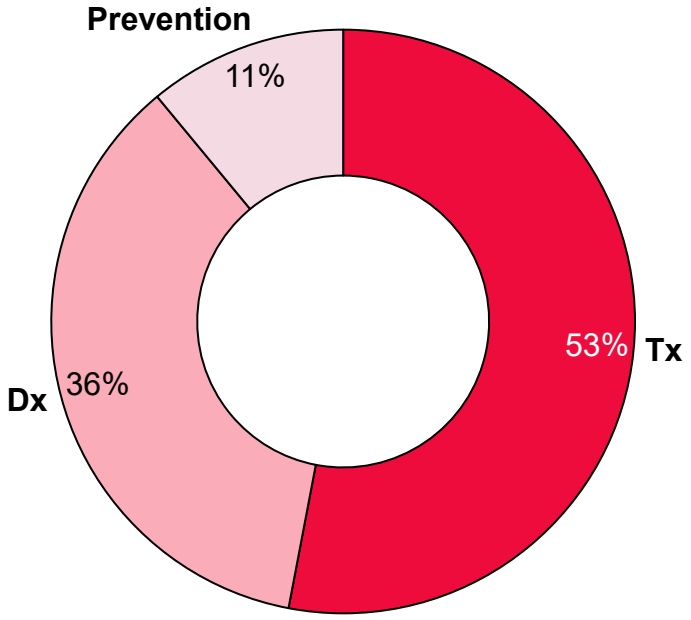
Data sharing classification: Limited distribution
Data steward: **Aaron Flores**
Data owner: Martin Auton

ARV Category

ARV: Treatment remains a key element however focus on prevention & Dx has led to demand increases

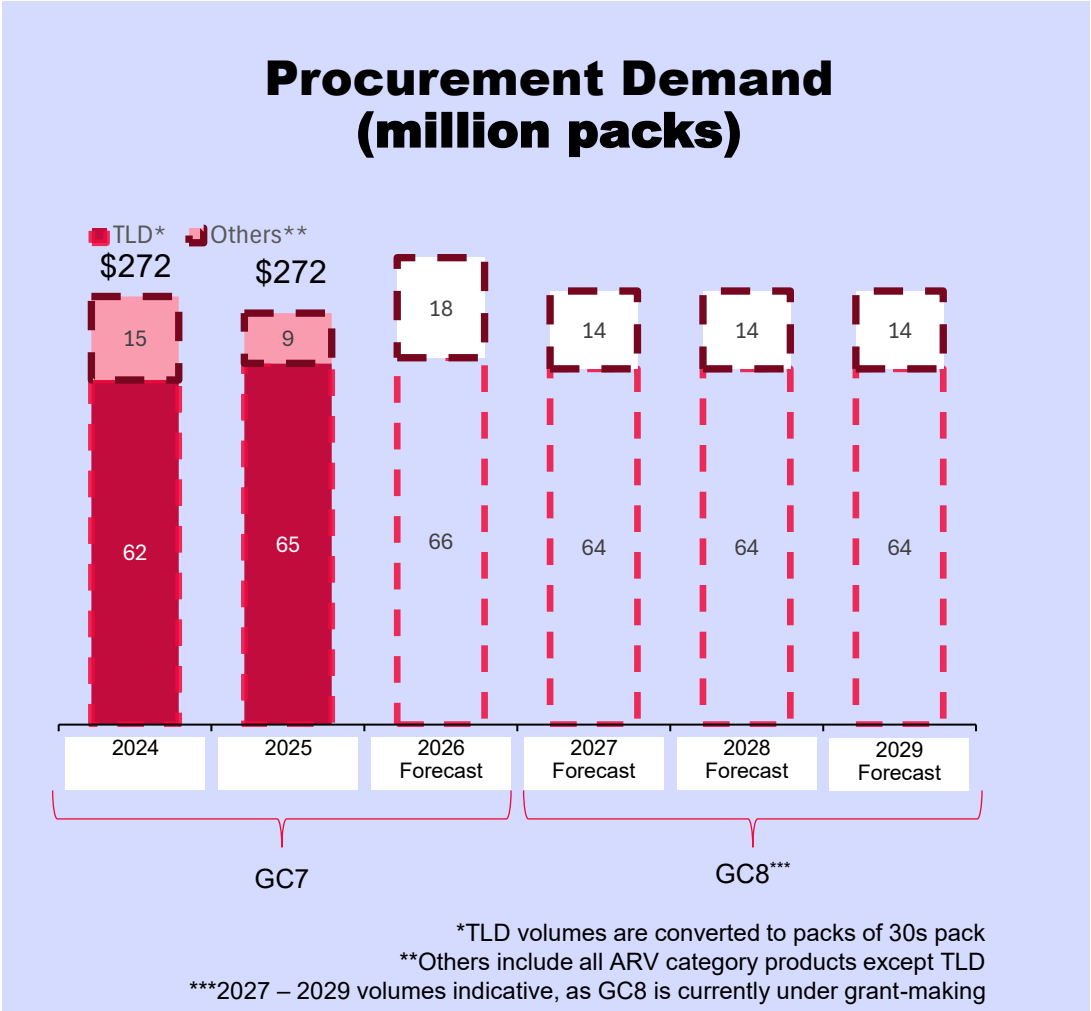
1. **Treatment continues to dominate ARV spend**, with the Global Fund accounting for **~26% of the global market (2024)**.
2. **Spend mix is shifting** prevention and diagnostics have grown materially since 2020, while treatment's spend share has declined, however volumes remain consistent.
3. **Although the portfolio includes 70+ SKUs**, seven products account for over 90% of total volume and value.
4. **Innovation is central to future impact and relevance**, with new modalities (e.g., Cab-LA, Lenacapavir) supporting country program evolution.
5. **Increase in prevention demand** is expected to continue in the coming cycle.

PPM HIV Portfolio:
USD 418 million spend 2025



ARV Demand Remains Stable with TLD as the Backbone

1. **Demand is expected to remain stable** in the next grant cycle with an expected increase in demand possible driven by non-grant funding.
2. **Lower volumes in 2024–25 do not reflect weaker demand**, but result from inventory overstocking, longer shelf life.
3. **Expanded WHO Recommendations** not expected to materially impact overall demand. **TLD remains the backbone of the portfolio,** representing ~82% of the ARV portfolio spend
4. **Prevention demand** is expected to further increase in the next Grant Cycle

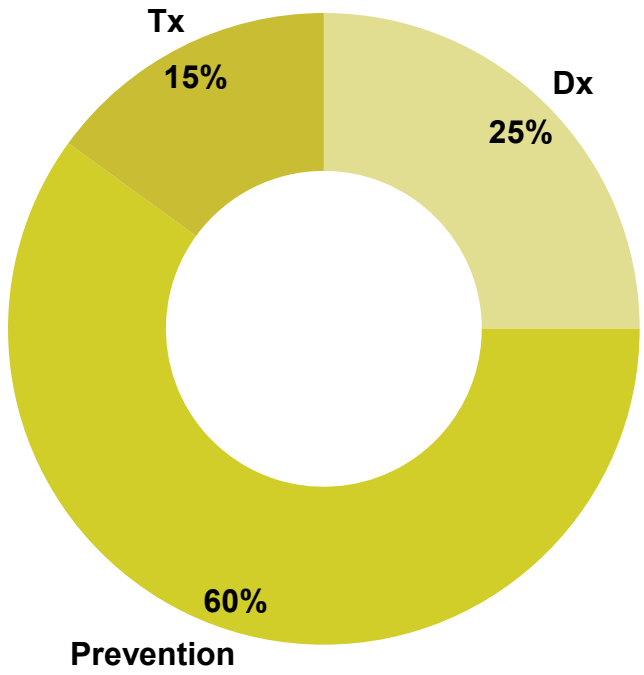


ANTM Category

Prevention Leads ANTM Portfolio as Resistance Shifts Treatment Demand

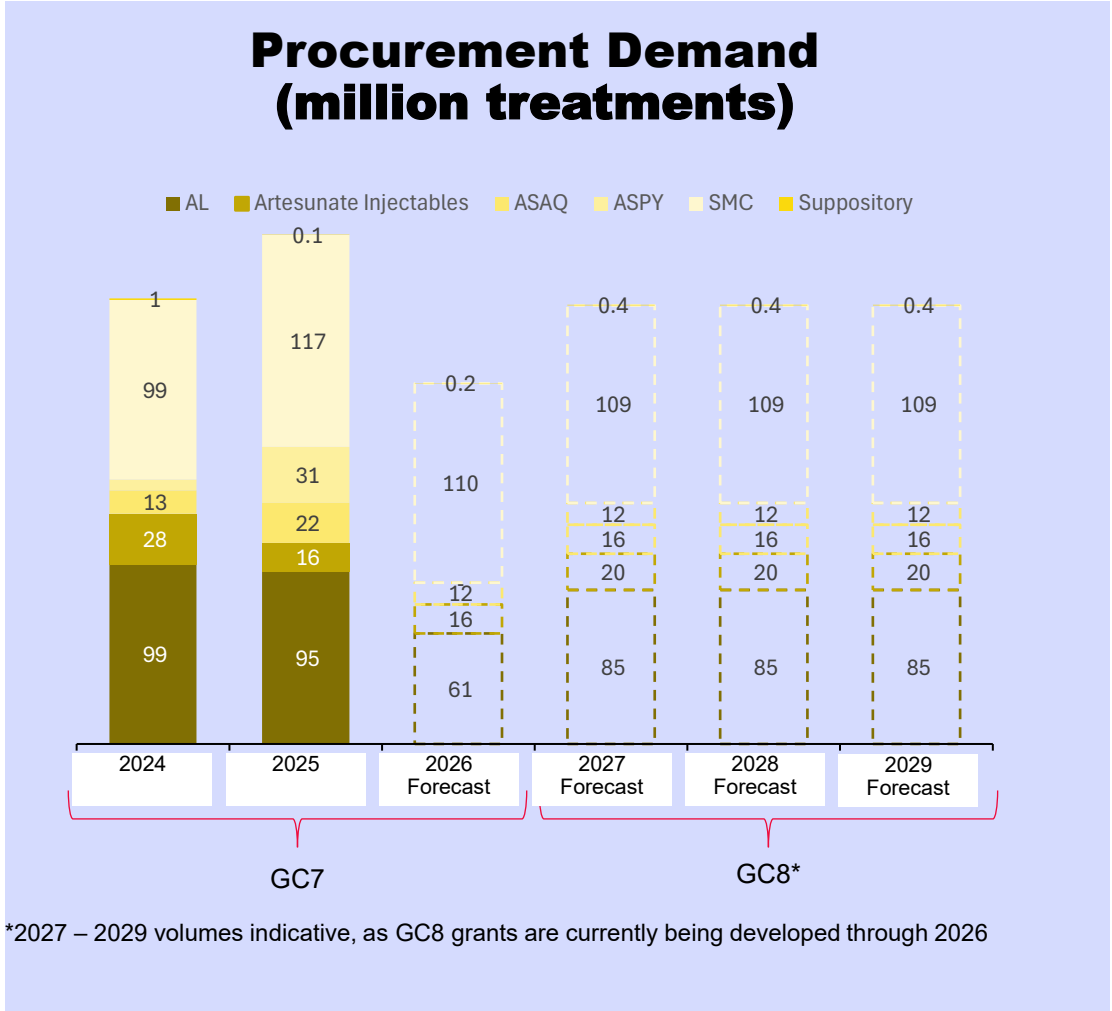
1. **The ANTM pharma portfolio spend** is on average ~$123M annually
2. **Prevention Chemotherapy, mostly through Seasonal Malaria Chemoprevention (SMC),** remains the key driver of the Global Fund's malaria prevention strategy.
3. **Growing antimalarial drug resistance will change demand** for first line treatments in the next tender cycle as countries diversify their portfolios
4. **Increase in prevention spend is** driven by several factors including new product introductions outside pharma (e.g.dual a.i. nets)

PPM Malaria Portfolio:
USD 323 Million Spend 2025



Demand remains steady as diversification strengthens protection against emerging resistance

1. **Demand is expected to remain stable** in the next grant cycle with a shift in first line therapies & potential increase in demand driven by non-grant funding
2. **AL remains the predominant ACT** however uptake of alternative ACTs through coordinated market shaping will be used to address barriers to adoption & drive alternative first line product uptake.
3. **Portfolio optimization exercises are on-going** to reduce the number of SKUs and create further efficiencies for supplier capacity planning.



*2027 – 2029 volumes indicative, as GC8 grants are currently being developed through 2026

NB: CPM not included in treatment numbers

Pharma Sourcing Strategy (2027-2029)

Cathal Meere

Manager Pharma Sourcing

Pharma Tender 2027-2029: The Global Fund's Sourcing Strategy is closely aligned with Organizational Market Shaping Goals



1. **Sustain Affordable, Equitable & Secure Access to Life Saving Medicines**. Maintain multi-sourcing approach while concentrating volumes where appropriate, protect supply resilience through smart portfolio and pricing management

2. **Drive Accelerated Access to New Products & Shape Innovations:** Support faster introduction of new and emerging products through clear signaling, early engagement & coordinated planning



3. **Strengthen Regional Manufacturing Capacity building:** Reinforce long term supply resilience, Increase procurement from regional manufacturers through procurement collaborations and capacity building partnerships, leveraging our sourcing tenders



4. **Continued Quality & Compliance adherence:** Ensure quality assurance and compliance remain foundational, supporting secure and reliable access—not operating as barriers

5. **Extend access to pricing and terms for domestic and partner financing** through the non-grant funded procurement channel of PPM/wambo. Increased strategic procurement collaborations similar to the PAHO partnerships

Objective 1: Sustain Affordable Access to Life Saving Medicines

1. **Strengthen post-award governance** including robust contractual terminology based on accountability**,** protect OTIF & ensure secure supply with proactive issue escalation

2. **Continued focus on demand visibility & order placement timing**, more closely aligned with supplier capacity planning to further unlock supply chain value

3. **Optimize Supply Portfolio** by key volume and value drivers; tail end products are transitioned to more optimal regimen

4. **Access to pricing and terms for domestic and partner financing** through the non-grant funded procurement channel of PPM/wambo will be a tender requirement and mandatory in contracts

5. **Dual window tender approach will allow suppliers to submit offers on products that are not yet QA compliant**. These will be evaluated through the tender process, including contractual signature, but will become effective only once the product becomes compliant.

Objective 2: Drive Accelerated Access to New Products & Shape Innovations

1. **Actively shape pricing and accelerate scale-up:** Utilize targeted market-shaping tools to bridge early pricing gaps, create competitive conditions, and shorten regulatory timelines—so new products & products with limited number of supplier can reach scale faster.
2. **Drive first-line ANTM diversification**: Shift a defined share of ACT demand toward alternative therapies (ASPY, DHA/PPQ) through tender allocation, partner alignment, and country engagement to manage resistance and reduce dependency on AL.
3. **Establish targeted reserve pools**
   Create volume pools to support innovation & access as products become eligible, support supplier investment, and enable rapid onboarding of approved products.
4. **Include Special Contracting terms**
   Apply selective contractual levers (e.g., volume signals, phased allocations, capacity commitments) to secure supply resilience and accelerate adoption of new therapies where appropriate.

Objective 3: Strengthen Regional Manufacturing Capacity Building

1. **Embed regional manufacturing into the tender evaluation framework**
   We will strengthen and adapt evaluation criteria so that regional manufacturing capability becomes a meaningful differentiator—rewarding suppliers who invest in sustainable, high-quality local capacity.

2. **Build a dedicated demand pool to anchor regional supply**
   A defined share of forecasted volumes will be defined for qualified regional manufacturers, providing the predictability needed for long-term investment and capacity expansion.

3. **Provide forward visibility on order placement to enable capacity planning**
   We will share clearer timing signals and procurement calendars so regional manufacturers can plan production, manage API and raw material requirements, and improve supply reliability.

4. **Target markets where regional production offers strategic advantage**
   We will identify product categories and geographies (e.g., lower landed cost markets, alternative Incoterms, aligned regulatory pathways) where African-based manufacturers can compete and deliver resilience benefits.

5. **Leverage the tender as a market-shaping tool to grow regional ecosystems**
   Beyond procurement through our catalytic investments, we will continue to incentivize investment, improve regulatory readiness, strengthen quality systems, and build an integrated regional supply base aligned with long-term Global Fund priorities.

* * *For this tender, "Regional Manufacturing" refers to manufacturers undertaking full or partial pharmaceutical manufacturing processes within Africa for products that meet the Global Fund's Quality Assurance Policy requirements.*

Objective 4: Quality & Compliance as Enablers

1. **Achieving and maintaining the required quality standards** remains essential and directly impacts supply chains and access to life-saving medicines. Non-compliance with QA standards and Environmental, Social, and Governance (ESG) requirements carries a zero-tolerance disqualification risk.

2. **Compliance is a strategic asset** & Sourcing will continue to work closely with QA to ensure & maintain manufacturers' awareness and proactive ownership of compliance, including the immediate reporting of potential deviations and the effective implementation of CAPAs. The aim is to continuously strengthen suppliers' sustainability credentials and practices across their manufacturing sites and supply chains.

3. **Reinforce Market Surveillance** by supporting recipients in quality monitoring activities through provision of validated analytical methods and reference substances.

Objective 5: Drive scale synergies across grant and non-Global Fund financed procurement

1. Expand non-Global Fund financed procurement (NGFP)

We adapt contractual clauses to simplify the onboarding of new Principal Recipients, widening access to Global Fund pricing and terms.

2. Extend pricing and terms to domestic and partner financing

Through the non-grant funded procurement channel of PPM/wambo, with increased strategic procurement collaborations

3. Apply special contracting terms

Market access to pricing and terms through PPM/wambo a tender requirement and mandatory in contracts, using selective contractual levers where required to support countries transitioning to domestic financing.

Request for Proposals (RFP) Approach & Timeline

Marlène Coffy
Associate Specialist Global Sourcing Pharmaceutical

Procurement Process and Timelines *(indicative)*

Phase I: RFP Launch (March 2026)

- RFP is launched through the Fusion Platform
- Bidder Q&A on the RFP process and documents

Phase II: Submissions and Evaluations (March/April 2026)

- Receive technical and commercial submissions
- Evaluation (QA eligibility, bid completeness, market shaping considerations)
- Commercial negotiations
- Final bid (BAFO) submission from bidders

Phase III: Evaluations (June – July 2026)

- Final Bid Evaluations to inform the RFP outcome proposal
- Internal Approval
- Award

Phase IV: Contracting (September – October 2026)

- Supplier Notification of Award
- Contract finalization & signature

Tender Evaluation Structure *(indicative)*

Pharma RFP

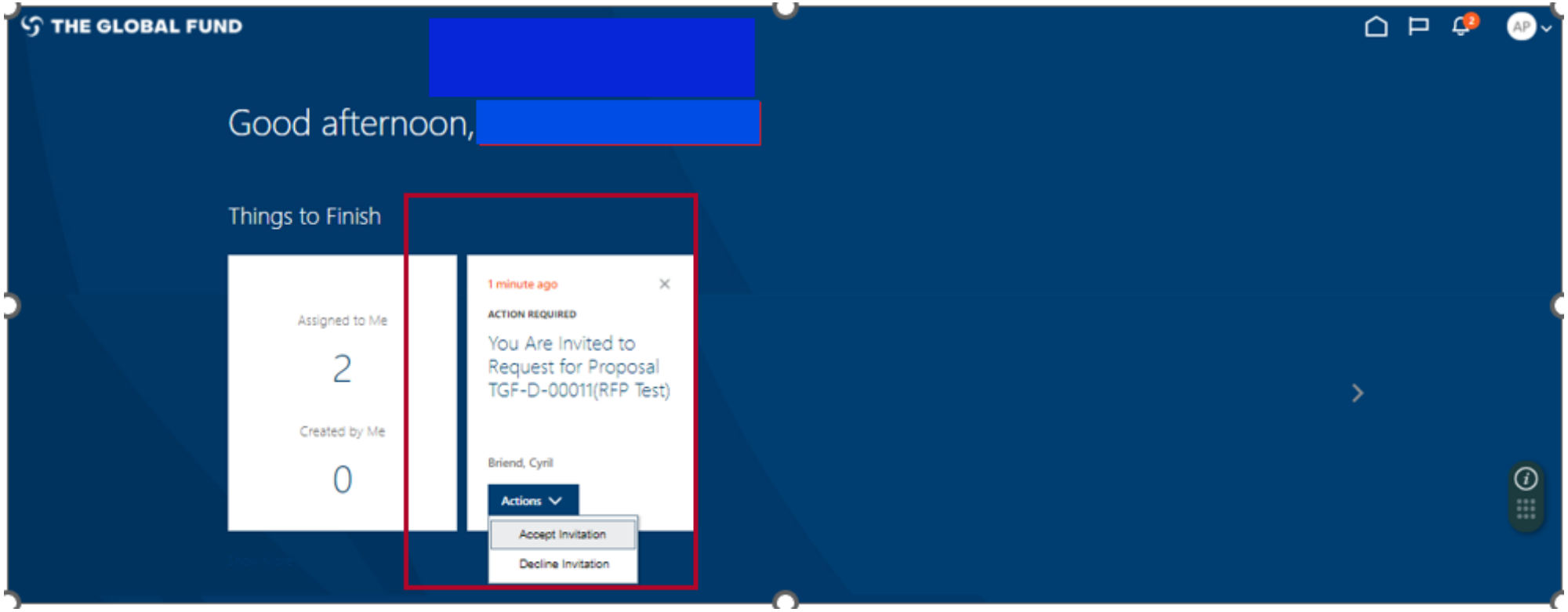
Commercial (45%)	Technical (55%)
Base Price and Total Landed Cost	1. Product Coverage
Compliance requirements: • **Financial Due Diligence** • **Integrity Due Diligence**	2. Innovation
	3. Supply Security and Visibility
	4. OTIF delivery performance
	5. Country Registration Coverage

- **The full scope of evaluation criteria** will be **reapplied at annual performance reviews** for subsequent allocation periods
- There will be **a process** to consider **new entrants and/or new products** that become **eligible** for procurement **after tender closure (subject to review)**
- Regional Manufacturing information will be requested and used as part of the evaluation*

* *For this tender, "Regional Manufacturing" refers to manufacturers undertaking full or partial pharmaceutical manufacturing processes within Africa for products that meet the Global Fund's Quality Assurance Policy requirements.*

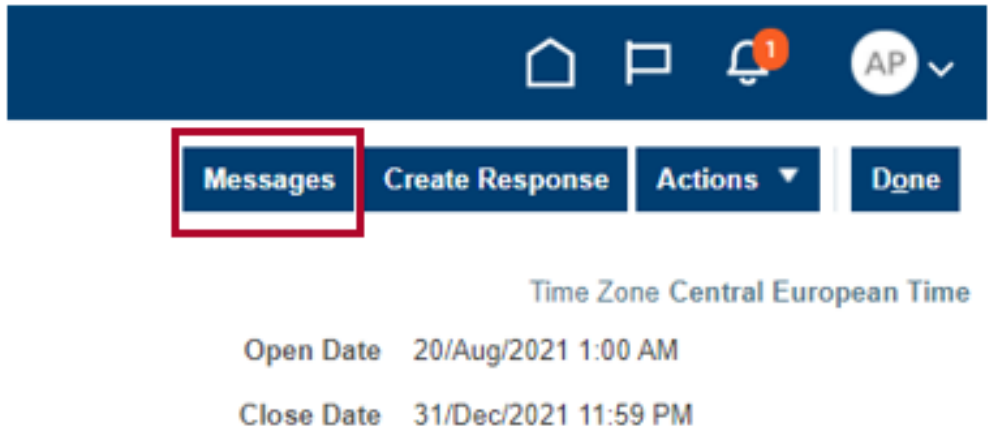
Sourcing Platform used for all RFP communications

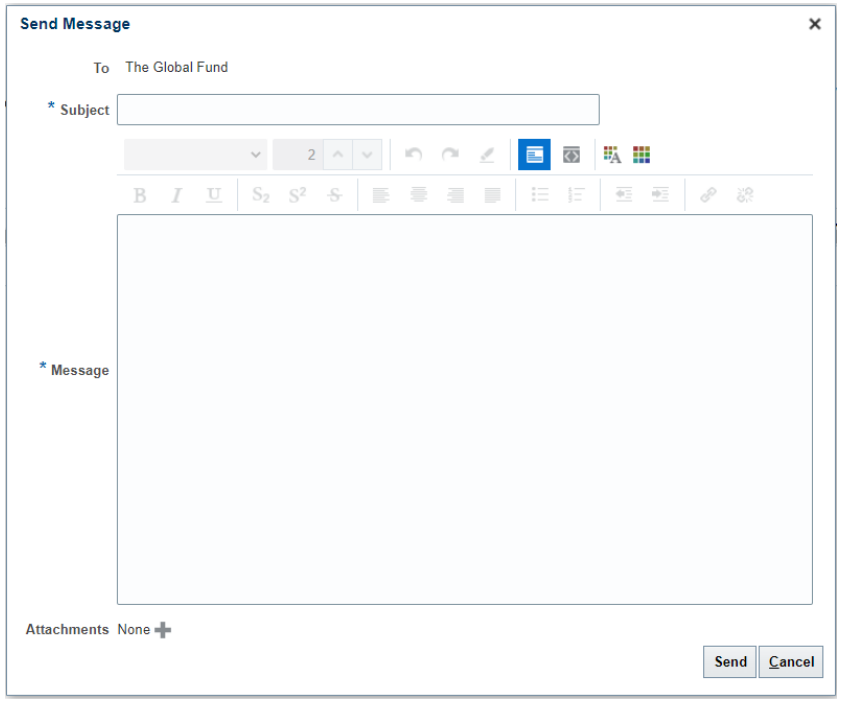
Welcome page & Notifications



Communications & Support on Platform Access

- **All communications with regards to the RFP**, including clarification questions, shall be in writing and sent through the TGF Sourcing Platform using the online discussion (see below).
- Any communication from an RFP Participant to the Global Fund related to the RFP which is **not** through the designated channel (https://fa-enmo-saasfaprod1.fa.ocs.oraclecloud.com/), is not permitted and will not be answered.
- Should the Global Fund deem it necessary to revise the RFP as a result of a clarification, it shall do so as an amendment to the RFP available on the Global Fund's website.





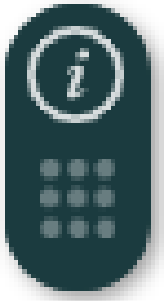
Sourcing Platform: Other Matters

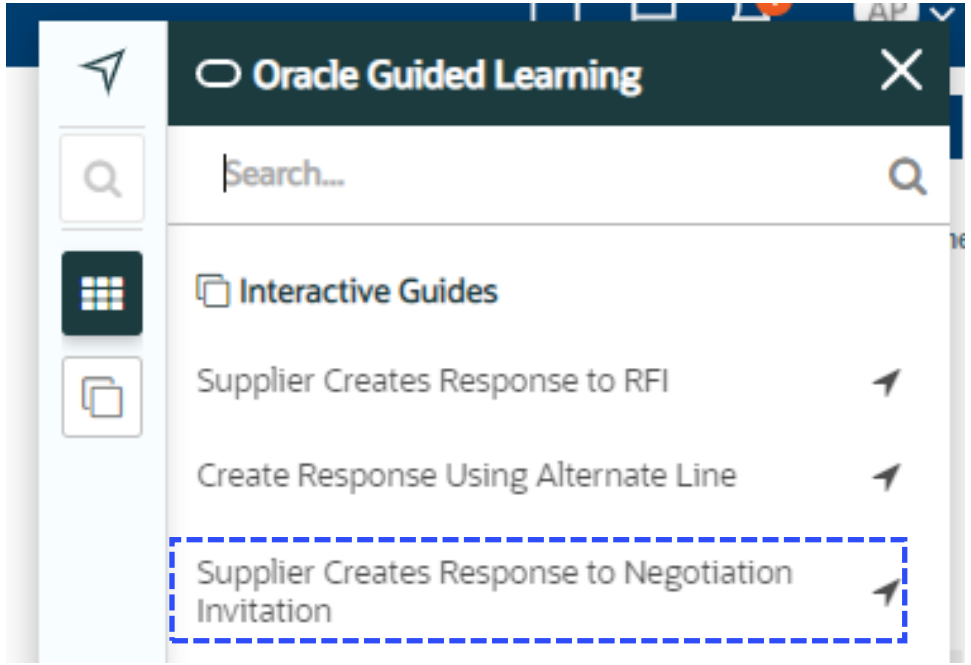
Oracle Guided Learning (OGL)

- Feature which provides step-by-step and personalized guides in the negotiation module.

- Please open the following link in your browser to see the step guide (Supplier Creates Response to Negotiation Invitation):
  https://guidedlearning.oracle.com/player/latest/api/scenario/export/v1/WpUIM+OJRoSJYo3jQu37UA/k7hjkrg1/lang/--/?draft=undefined

- Access to the OGL: Click on the “I” icon and select the appropriate Guide





Quality Assurance Requirements

Sandrine Cloez

Specialist Quality Assurance Pharmaceuticals products

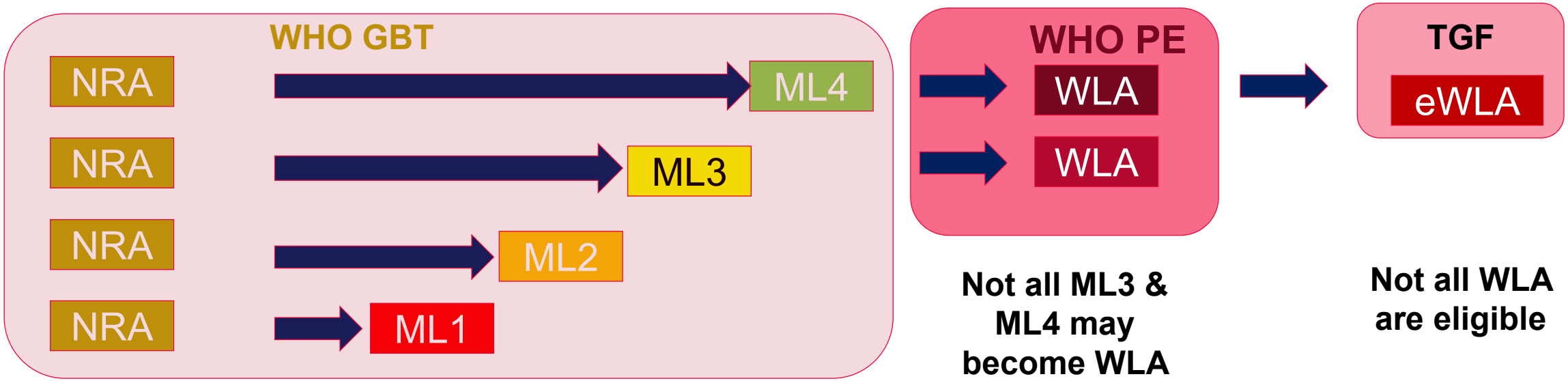
QA Requirements Pharmaceutical Products

Reference	QA Policy for Pharmaceutical Products
Product applicability	For all pharmaceutical products
Clinical requirements	Medicines listed in current National STG/EML or WHO STG/EML or WHO rapid communication
Registration & Authorization Quality Requirements	1. Authorized by NRA And only for ARVs, Anti-TB and Antimalarial Finished Pharmaceutical Products 2. Prequalified by the WHO Prequalification Programme OR Authorized for use by SRA OR Authorized for use by WHO Listed Authority (WLA)(1) OR Recommended for use by Expert Review Panel For Emergencies (PHEIC)(2) Approved under the WHO Emergency Use Listing OR Under SRA/WLA Emergency procedures

(1) WLA with the registration and marketing authorization, regulatory inspection and vigilance functions within its scope of listing, as published and regularly updated on the WHO website
(2) Board approval required

WHO Listed Authorities (WLAs) for Finished Pharmaceutical Products

- National Regulatory Authority who has been benchmarked towards the Global Benchmarking Tool (GBT) as Maturity Level 3/4 AND satisfied the Performance Evaluation (PE) as performed by WHO
- It can be :
  1. A standalone National Regulatory Authority **OR**
  2. A System of (more than one) National Regulatory Authorities



What is the situation on WLA (1) at end of 2025

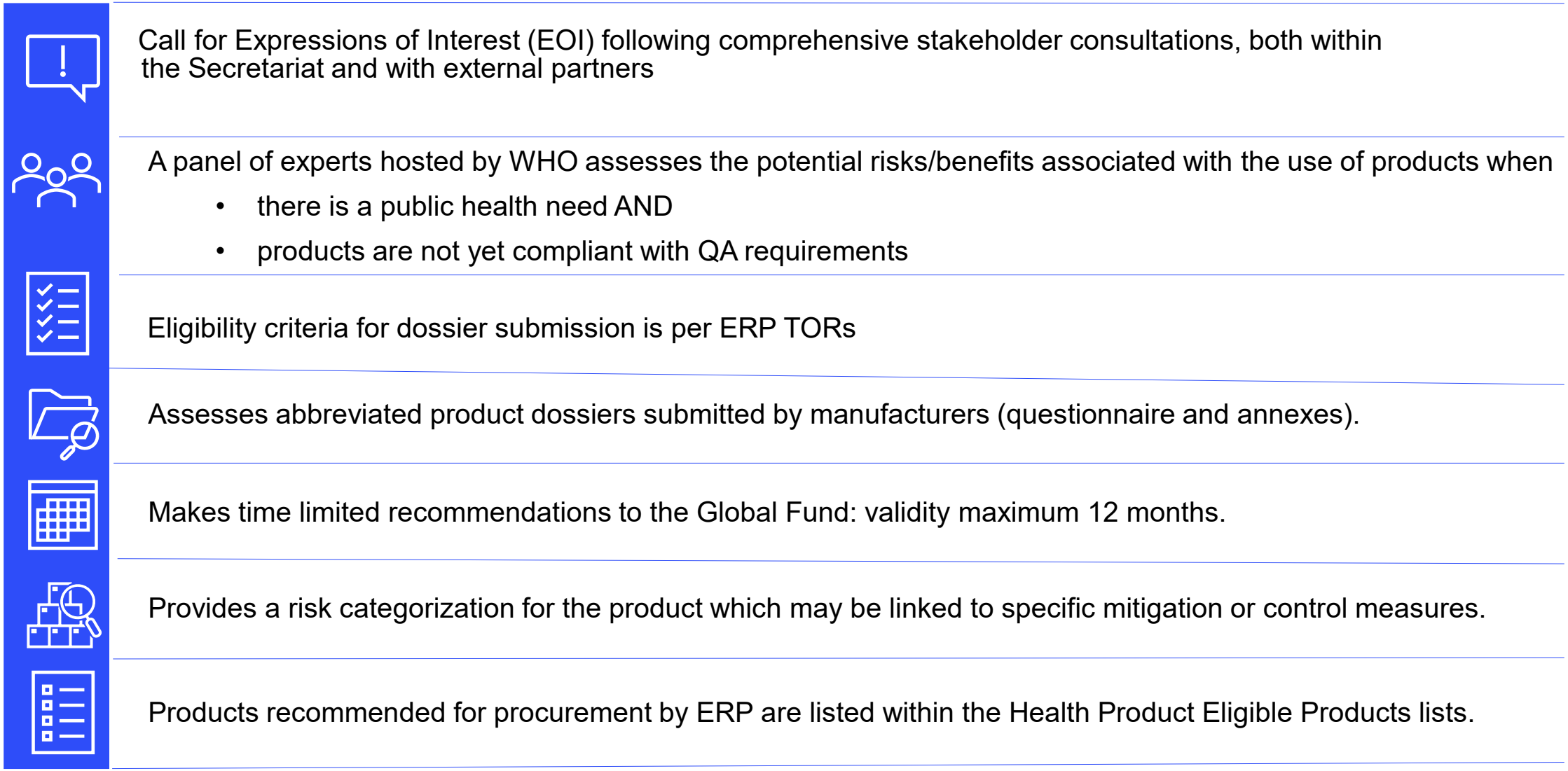
ML3 - Medicines	ML4 -Medicines	WLA- Medicines (2)	Eligible WLA (3)
Ghana-Food and Drugs Authority Nigeria-National Agency for Food and Drug Administration and Control Tanzania-Tanzania Medicines and Medical Devices Authority Türkiye-Turkish Medicines and Medical Devices Agency (TİTCK) Egypt- Egyptian Drug Authority (EDA) Rwanda Food and Drugs Authority (Rwanda FDA) Sénégal-Agence sénégalaise de Réglementation Pharmaceutique) Zimbabwe- Medicines Control Authority of Zimbabwe (MCAZ) Ethiopia- Ethiopian Food and Drug Authority (EFDA)	Singapore-Health Sciences Authority Rep. Korea-Ministry of Food and Drug Safety Saudi Arabia-Saudi Food and Drug Authority	Singapore-Health Sciences Authority Rep. Korea-Ministry of Food and Drug Safety Former SRA	Singapore-Health Sciences Authority Rep. Korea-Ministry of Food and Drug Safety Former SRA with registration, marketing authorization, regulatory inspection, and vigilance functions

(1): No WLA for MD and IVDs at present

(2): WLA for vaccines should not be considered as eligible

(3): Only NRAs having the regulatory function of registration and marketing authorization, regulatory inspection and vigilance functions in their scope of listing are eligible

The Expert Review Panel (ERP)



Call for Expressions of Interest (EOI) following comprehensive stakeholder consultations, both within the Secretariat and with external partners

A panel of experts hosted by WHO assesses the potential risks/benefits associated with the use of products when

- there is a public health need AND
- products are not yet compliant with QA requirements

Eligibility criteria for dossier submission is per ERP TORs

Assesses abbreviated product dossiers submitted by manufacturers (questionnaire and annexes).

Makes time limited recommendations to the Global Fund: validity maximum 12 months.

Provides a risk categorization for the product which may be linked to specific mitigation or control measures.

Products recommended for procurement by ERP are listed within the Health Product Eligible Products lists.

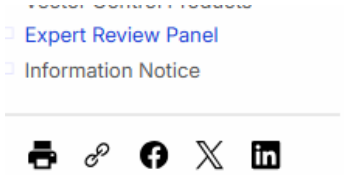
ERP review classifies products into 4 risk categories with corresponding procurement implications

ERP Risk category		Procurement implication
Risk category 1	✓	May be considered for time-limited procurement
Risk category 2	✓	May be considered for time-limited procurement
Risk category 3	○	May be considered for time-limited procurement **only if** there is no other option & if benefit outweighs the risks of not administering the drug
Risk category 4	✗	May not be considered for procurement under any circumstances.

ERP EoI calls

- Two ERP rounds per year (EoI call March and July)
- Ad Hoc ERP open EoI call

Expert Review Panel



reference are available under related resources.

- Expert Review Panel for Vector Control Products, the panel's terms of reference are available under related resources.

Opportunities for Evaluation

Manufacturers are invited to submit their products for Expert Review Panel evaluation upon publication of a request for Expression of Interest. Invitations are published as either semesterly Round calls with a submission deadline or Ad-Hoc with no specified deadline. We regularly publish all invitations on our Updates page. The continued Ad-Hoc invitations are also found in the drop down lists below:

— **Opportunities for Evaluation of Medicines**

Antituberculosis Medicines: Bedaquiline 20 mg, tablet, (scored and dispersible); Delamanid 50mg, tablet; Rifapentine / Isoniazid / Moxifloxacin / Pyrazinamide, 300 mg / 75 mg / 100mg / 375 mg tablet; Rifapentine / Isoniazid / Moxifloxacin, 300 mg / 75 mg / 100mg tablet
(GF/ERP/Ad-Hoc/07-2025)

download in English

Global Fund List

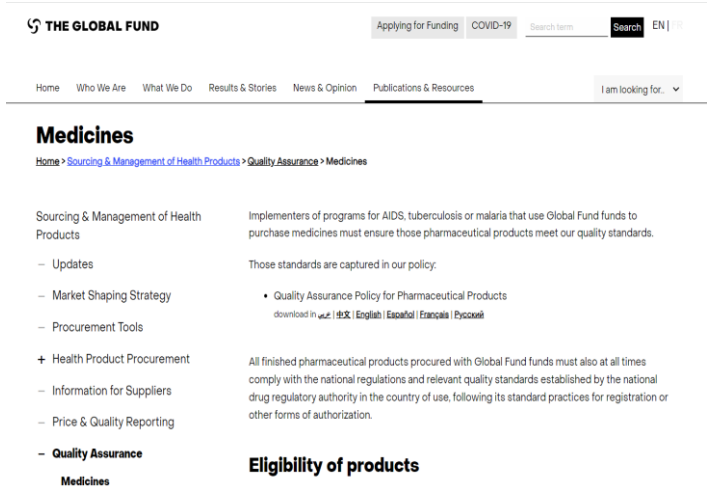
An overview of products and manufacturers classified according to the Global Fund QA Policy criteria:

- WHO prequalified;
- WLA/SRA approved;
- ERP-reviewed product - Cat 1 and 2.

➢ List is updated regularly, usually at the end of each quarter

Published on the Global Fund webpage:

Medicines Qualitiy Assurance



THE GLOBAL FUND

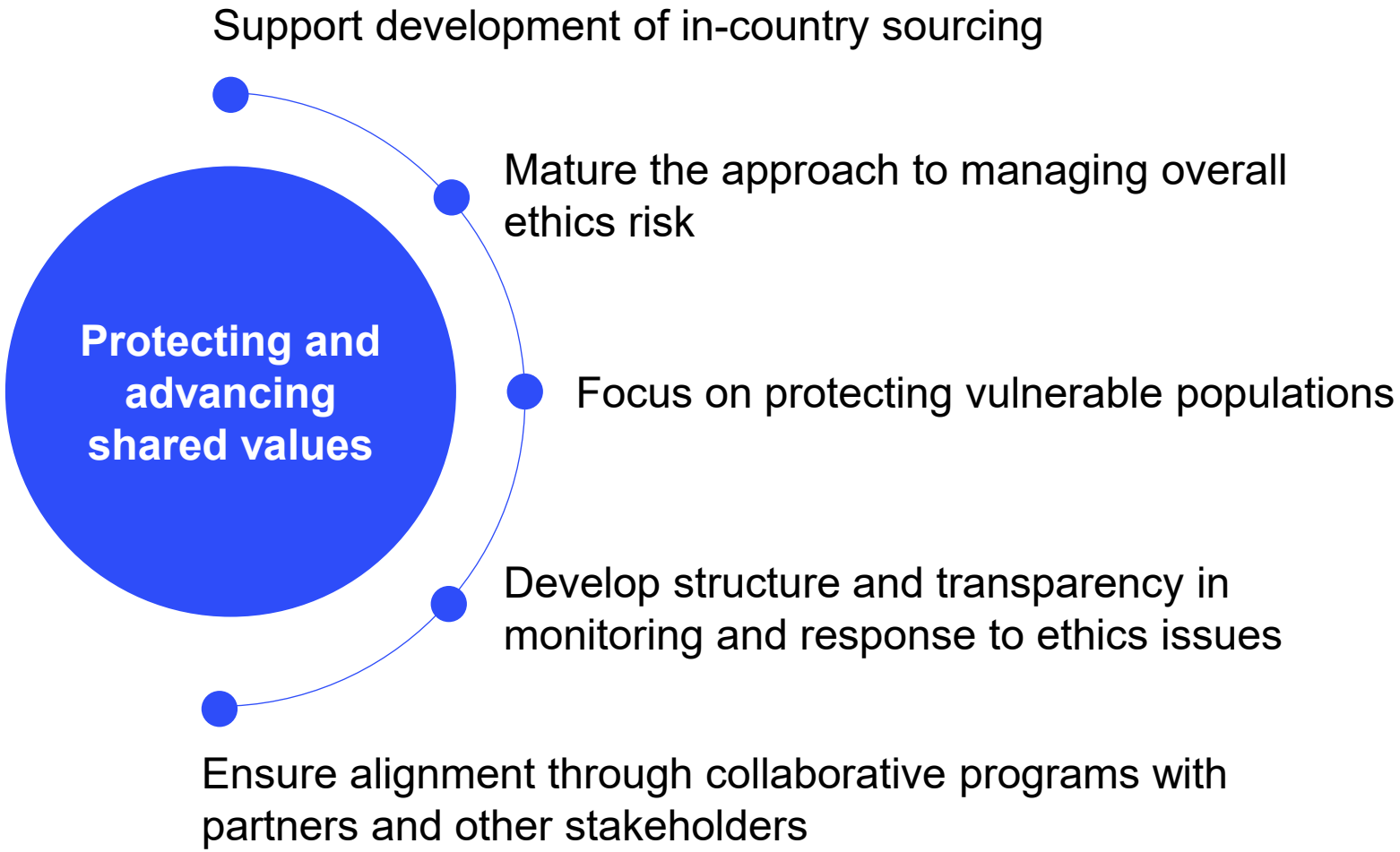
Integrity Due Diligence

Artem Lazurenko

Specialist Ethics, Risk Management

Ethics in Grant Cycle 8

Supporting the strategic shifts of GC8 in a developing risk context



Integrity Due Diligence

Guiding policies

Ethics and Integrity

- **Code of Conduct for Suppliers**

Bidders required to sign as a part of contracting or provided aligned internal policies covering the relevant activities

Defines prohibited practices in human rights, fiduciary and conduct topics and requires operationalized prohibitions at supplier level

- **Integrity Due Diligence Framework**

Questionnaire on ownership, control and internal policies issued to all Bidders

Responsible Procurement

- **Responsible procurement framework**

A Global Fund-level framework for a holistic approach to integrating environmental and societal risk management into sourcing.

Bidders expected to enact ISO or equivalent standards and participate in ESG reporting activities to facilitate responsible procurement

- **Vendor monitoring**

As a part of regular sourcing activities, the Global Fund will monitor supplier track record and may implement additional metrics in line with the framework

Integrity Due Diligence

Focus on emerging risks

Bribery and corruption	Bidders required to define and prohibit both alongside a wider set of prohibited practices as per the Policy to Combat Fraud and Corruption. Increased risks due to constrained resource environments, partner pull-outs and focus on in-country sourcing.
Sexual exploitation, abuse and harassment	Bidders required to define and prohibit these, alongside child protection. Increased focus on risk as a part of the development sector campaign to protect vulnerable populations, which are becoming increasingly exposed.
Sanctions	Bidders must not be subject to restrictive measures. Rapidly evolving sanctions environment due to geopolitical instability requires close attention and rapid reporting of changes

Break

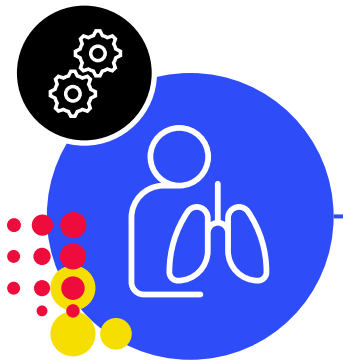
Global Fund TB Update Priorities for GC8

Dr. Grania Brigden

Senior TB Advisor

TB Investment Approach

Examples from the section on TB screening and diagnosis (not exhaustive)



Priorities for Global Fund investments

- Implement screening and diagnostic algorithms that are sensitive, accurate and efficient, such as CXR with CAD/AI for TB screening, rapid molecular test as the initial test for TB
- Prepare for introduction and scale-up of new tools including near-point-of-care tests and alternative sampling techniques recommended by WHO.
- Intensify screening and testing for TB in health facilities, including quality improvement
- Integrate TB services into essential healthcare packages and systems
- Implement targeted active case finding focused on key and vulnerable populations,

Lower priority for Global Fund investments

- Limit the use of sputum microscopy to monitor treatment progress rather than for TB diagnosis
- Limit mass chest camps among the general population or untargeted active case finding interventions, particularly those that have not demonstrated the expected yield of TB cases.

Optimization, efficiency and other considerations

- Consider mapping and targeting high-risk groups and geographic areas with high incidence (“hotspots”) using available data, including vulnerability index.
- Consider options to optimize the use of test cartridges, such as pooling of sputum samples for mWRD tests and upfront use of x-rays (with CAD) for TB screening.

Examples of prioritization for GC8

(not exhaustive)

Topic	Priority intervention	Lower priority
Screening & Diagnosis	• CXR, CAD/AI, mWRD, **NPOC,*** LF-LAM • Integrate TB into PHC packages & systems • **Sample pooling***	• Sputum microscopy for diagnosis • Non-performing ACF campaigns
Treatment	• DS-TB: 2HRZE/4HR, 2HRZ(E)/2HR • DR-TB: 6-month BPaLM, **BDLLfxC**	• DSTB: 2HPMZ/2HPM for people ≥12 yrs • **DR-TB: 9-m BLMZ, BLLfxCZ and BDLLfxZ**
Prevention	• Antigen-based TB skin test • TPT for household contacts ≤ 5 years and PLHIV • Preparation for **TB vaccine introduction**	• Interferon-Gamma Release Assay tests • TBI testing and TPT for older household contacts and other risk groups
Strategic Information	• Real-time, digital case-based TB surveillance system strengthening, interoperability • Routine and periodic data analysis & use	• Only in **exceptional circumstances:** TB prevalence surveys, household cost surveys, KAP surveys, operational research
Crosscutting	• Included in KVP: people in **fragile and conflict-affected settings**, affected by **extreme weather events & climate impacts** • Health products: use standardized product specifications, optimize procurement channels	• Purchase of vehicles and non-essential equipment, renovations, international conferences, commemorative days, generic mass media events. Optimize trainings, meetings, supervision.

*NPOC eligible for GF procurement. NPOC and sample pooling just received WHO guidance

THE GLOBAL FUND

WHO: Global HIV, Hepatitis and Sexually Transmitted Infections Programs

Marco Antonio Vitoria

Medical Officer – Treatment and Care Team

Updated WHO ART recommendations and perspectives on the future of extended-duration treatments

Marco Vitoria

Department of HIV, TB, Hepatitis and STIs

World Health Organization

2025 ART recommendations

ART topic	Previous recommendations	2025 recommendations
Preferred and alternative PI options	• ATV/r and LPV/r as preferred PI options • DRV/r as alternative PI option	• DRV/r as **preferred PI option** • ATV/r and LPV/r as **alternative PI options**
Preferred and alternative NRTI options for initial regimens	• TDF as preferred option for ART initiation in adults and adolescents • ABC as preferred NRTI option for ART initiation in children • AZT or TAF as alternative options or used in special circumstances	• **Adults, adolescents and children > 30 kg: TDF or TAF as preferred option** in initial and subsequent regimens (even if TDF or AZT previously used) • **Children < 30 kg: ABC as preferred** option in **initial** regimens. **ABC or TAF as preferred** options in **subsequen**t regimens (even if ABC or AZT previously used)
NRTI sequencing in subsequent regimens	• AZT in subsequent regimen if TDF or ABC used in initial regimen (and vice-versa)	
Dual ARV oral regimens NEW	• No recommendation	• DTG+3TC as **ART simplification** strategy in adults and adolescents with undetectable HIV viral load and without active HBV infection
Long-acting ARV injectable regimens NEW	• No recommendation	• CAB + RPV as alternative **ART switching** option in adults and adolescents with undetectable HIV viral load and without active HBV infection

Preferred and alternative initial ART regimens in adults, adolescents, children and neonates

Populations	Preferred initial regimen	Alternative initial regimen	Special circumstances
Adults and adolescents	TDF (or TAF) + 3TC (or FTC) + DTG	TDF + 3TC + EFV 400mg [a]	TDF (or TAF) + 3TC (or FTC) + EFV 600mg [a] AZT + 3TC + EFV 600mg [a] ABC + 3TC + DTG TDF (or TAF [b])+ 3TC (or FTC) + DRV/r (or ATV/r or LPV/r)
Children	ABC + 3TC + DTG	TAF + 3TC (or FTC) + DTG ABC + 3TC + DRV/r[c] (or ATV/r or LPV/r [e])	ABC (or AZT) + 3TC + EFV [d] (or NVP) AZT + 3TC + DRV/r [c] (or ATV/r or LPV/r [e])
Neonates	ABC + 3TC + DTG [g]	AZT + 3TC + NVP	AZT (or ABC) + 3TC + LPV/r [f]

3TC = lamivudine, ABC = abacavir, ATV/r = atazanavir/ritonavir, AZT= zidovudine, DRV/r = darunavir/ritonavir, DTG = dolutegravir, EFV = efavirenz, FTC= emtricitabine, LPV/r = lopinavir/ritonavir, NVP = nevirapine, TAF = tenofovir alafenamide, TDF = tenofovir disoproxil fumarate

a. EFV-based ART should not be used in settings where national estimates of pre-treatment resistance to EFV are 10% or higher.
b. In adults and adolescents, TAF daily dosage should be reduced from 25 mg to 10 mg when used with boosted PIs.
c. DRV/r is not approved for children under three years of age.
d. EFV should not be used for children younger than three years of age.
e. ATV/r can replace LPV/r for children over three months old, but consider limited formulations for those under six years, lack of fixed-dose, and separate ritonavir booster administration.
f. LPV/r syrup or granules can be used if starting after 2 weeks of age.
g. Dolutegravir (DTG) dose of 5 mg every other day (every 48 hours) in the first 2 weeks of life is safe and maintains appropriate drug levels. At age 2 weeks, DTG dosing is increased to 5mg once every day

Preferred and alternative subsequent ART regimens for adults, adolescents, children and infants

Population	Failing initial regimen	Preferred subsequent regimen	Alternative subsequent regimen
Adults, adolescents and children ≥ 30 kg	TDF (or TAF) + 3TC (or FTC) + DTG	**TDF (or TAF[a]) + 3TC (or FTC)** + DRV/r	TDF (or TAF[a]) + 3TC (or FTC) + ATV/r (or LPV/r) AZT (or ABC) + 3TC + ATV/r (or LPV/r)
	TDF (or TAF) + 3TC (or FTC) + EFV	**TDF (or TAF) + 3TC (or FTC)** + DTG	TDF (or TAF[a]) + 3TC (or FTC) + DRV/r (or ATV/r or LPV/r) AZT (or ABC) + 3TC + DRV/r (or ATV/r or LPV/r)
	AZT + 3TC + EFV	**TDF (or TAF) + 3TC (or FTC)** + DTG	TDF (or TAF[a]) + 3TC (or FTC) + DRV/r (or ATV/r or LPV/r) ABC + 3TC + DRV/r (or ATV/r or LPV/r)
Children < 30 kg and infants	ABC + 3TC + DTG	**ABC (or TAF) + 3TC (or FTC)** + DRV/r	TAF (or ABC) + 3TC (or FTC) + ATV/r[b] (or LPV/r) AZT + 3TC + ATV/r[b] (or LPV/r)
	ABC (or AZT) + 3TC + LPV/r	**ABC (or TAF) + 3TC (or FTC**) + DTG	ABC (or AZT) + 3TC + DRV/r[c]
	AZT + 3TC + NVP	**ABC (or TAF) + 3TC (or FTC)** + DTG	ABC (or TAF) + 3TC + DRV/r[c] (or ATV/r[b] or LPV/r)

3TC = lamivudine, ABC = abacavir, ATV/r = atazanavir/ritonavir, AZT= zidovudine, DRV/r = darunavir/ritonavir, DTG = dolutegravir, EFV = efavirenz, FTC= emtricitabine, LPV/r = lopinavir/ritonavir, NVP = nevirapine, TAF = tenofovir alafenamide, TDF = tenofovir disoproxil fumarate

a. In adults and adolescents, TAF daily dosage should be reduced from 25 mg to 10 mg when used with boosted PIs.
b. ATV/r can replace LPV/r for children over three months old, but consider limited formulations for those under six years, lack of fixed-dose, and separate ritonavir booster administration.
c. DRV/r is not approved for children under three years of age.

Comparison of TAF and TDF

Major parameters	Favors TAF	Favors TDF	Comments
Renal safety	✓		TAF shows less impact on renal and bone density mineral laboratory markers compared to TDF. Nevertheless, there is a low occurrence and non-significant difference in the incidence of clinical events when using TDF or TAF with unboosted regimens. There is a higher discontinuation rate due to renal events when using TDF with boosted PI regimens.
Bone safety	✓		
Dyslipidemia		✓	TAF associated with small increase in levels of LDL cholesterol and triglycerides.
Body weight gain		✓	TAF associated with small increase in body weight, particularly when used with INSTIs.
Use with boosted PIs	✓		TAF dose reduction is needed. Lower dose formulations of TDF are not available.
Use in people living with HIV with TB		✓	TAF has important drug interactions with rifamycins, but tenofovir diphosphate maintains therapeutic levels intracellularly.
Use in children	✓		TDF is not recommended for use in young children. TAF dosing for young children not established.
Accessibility in LMICs		✓	Both are available as generic FDCs, but TDF containing FDCs are largely available and at lower cost than TAF*.

FDC = fixed-dose combination, INSTI = integrase strand transfer inhibitor, LDL = low density lipoprotein, LMICs= low- and middle-income countries, PI = protease inhibitor, TAF = tenofovir alafenamide, TB= tuberculosis, TDF = tenofovir disoproxil fumarate, TLD= tenofovir+ lamivudine+ dolutegravir

*TAF has a high potential for price reduction if used at higher volumes, but it will have a relatively minor impact in the total cost of the regimen as current price of TLD is already very low and has been driven mainly by other drug components and very high volumes of TLD procurement.

New ART recommendations: Key Takeaways

Preferred initial regimens: TDF (or TAF) + 3TC (or FTC) + DTG for adults and adolescents; ABC+3TC+DTG for children (all ages).

Recycling TDF/XTC and ABC /3TC in subsequent regimens

DTG containing regimens continued to be the preferred option for second-line if DTG not used before. DRV/r as the preferred PI option when a PI is needed

DTG and DRV/r as core drugs in third-line regimens (with dose adjustments). ETR can be used as an alternative option, but no actual role for RAL.

Dual regimens (DTG/3TC and CAB/RPV) as simplification/swicthing options in specific circumstances

Expected drug procurement changes:

- Less demand for AZT and LPV/r,
- Increased demand for TAF, DRV/r, pALD
- demand for new ARV formulations (dual regimens) can be added for specific populations/situations (bit CAB/RPV availability very limited)

Pediatric ARV formulations in development:

- pDRV/r (120/20 mg),
- TAF/FTC/DTG for children < 15 kg (1.88/15/5 mg)
- Dispersible DTG/3TC (5/30 mg) tablets

Next steps in ART guidance



Sharing new ART guidelines through webinars and international conferences



Development of TPP for long-acting products (public consultation) and update of CADO/PADO priority lists



Providing guidance on managing TLD failure (including clinical use of INSTI resistance testing, drug exposure triage tests, and resuppressing strategies)



Monitoring real-world implementation data of new regimens

Long-acting ARV Pipeline in end of 2025

LA ARV class	Pre-clinical	Phase I	Phase II	Phase III
BNAbs		SAR441236 VH079 10E8.4/iMab VRC07-523LS (TMB-380)	Teropavimab (GS-5423; 3BNC117-LS) Zinlirvimab (GS-2872; 10-1074-LS) Lotivibart (VH38110-109; N6-LS) VRC01LS	
CD4 attachment inhibitor				Semzuvolimab (UB-421)
Capsid inhibitor		Lenacapavir (IM) VH-499 VH-280 GS-4182 TMB-365 GS-3107	VH280/VH499	Lenacapavir (oral)
CCR5 antagonist			Leronlimab (PRO-140)	
Fusion inhibitor			Lipovirtide	
Integrase inhibitor	GS-1219 GS-3242 BIC ULA (implant) DTG ULA (implant) CAB stearate (VH-310)	GS-6212 GS-1720 CAB ULA VH-184 STP0404		
NNRTI		RPV ULA	MK-8527 Ulonivirine (MK-8507) Elsulfavirine	
NRTI/NRTTI	Bavtavirine (GS-5894)	GS-1614 MK-8239		Islatravir (oral)
PI + NRTI		TLC 101 (LPV/r + TDF in DcNP)		
INSTI + NRTI	TLC 301 (TLD in DcNP)			

Adapted from WHO LA ARVs clinical landscaping report, 2025 (unpublished)

Major long-acting ARVs under investigation (Phase 2/3)

Drug Name	Drug Class	Route	Dose Schedule	Comments
Islatravir	**NRTTI**	**Oral**	**Daily/Weekly**	**Ongoing studies: ISL/LEN (weekly) and ISL/DOR (daily)**
Ulonivirine (MK 8507)	**NNRTI**	**Oral**	**Weekly**	**Antiviral activity against NNRTI resistance**
Lipovirtide	Entry inhibitor	Oral	Weekly	Also studied as every 2 weeks
GS 4182	Capsid inhibitor	Oral	Weekly	LEN prodrug **(study on hold)**
GS 1720	Integrase inhibitor	Oral	Weekly	Antiviral activity against DTG resistance **(study on hold)**
VH 184	Integrase inhibitor	SC	6/6 months	Antiviral activity against DTG resistance

Two studies in the ACTG of LEN/CAB approved

- **A5431-PALACE**:
  - Small trial (n=38) approved from the pharmaceutical companies of LEN/CAB in the ACTG
  - Inclusion criteria:
    - NNRTI resistance
    - Viremic
    - Experiencing adherence challenges with oral ART
- **A5433- LANCET**
  - Opening door to larger trial in LMICs
  - In those failing TLD due to adherence difficulties without suspicious for resistance (superiority study)
    - LEN/CAB vs TLD with enhanced adherence counseling

ACTG

Long acting ARVs: Key Takeaways

The landscape of long-acting HIV therapies is rapidly evolving, with a strong focus on less frequent dosing, new drug classes, and combination regimens.

Multiple phase 2 and 3 studies are underway, including combinations of LAIs and BNAbs, and new dosing strategies (e.g., weekly regimens, annual IM LEN for PrEP).

Several products are in preclinical and phase 1 stages, with a trend toward longer dosing intervals and combination therapies.

BNAbs are an important area of research, especially in combination with LAIs, but IV administration and need of susceptibility tests remain a challenge.

The field is dynamic, with new agents and formulations being tested for both treatment and prevention.

What is in the horizon?

- Once weekly oral regimens
  - ✓ Islatravir and lencapavir
  - ✓ Islatavir and ulonivirine
- New long -acting drugs/formulations in development (injectable and oral)
  - ✓ MK8527 – once monthly NRTTI
  - ✓ LEN once yearly , ultralong CAB (4/4 months)
  - ✓ CAB + LEN for **viremic patients**

What is in more long term ?

- Phase 1 new INSTI and capsid inhibitors (VH and GS prodrugs)
- LAIs (CAB, LEN) + bnAbs

Global Fund HIV Update

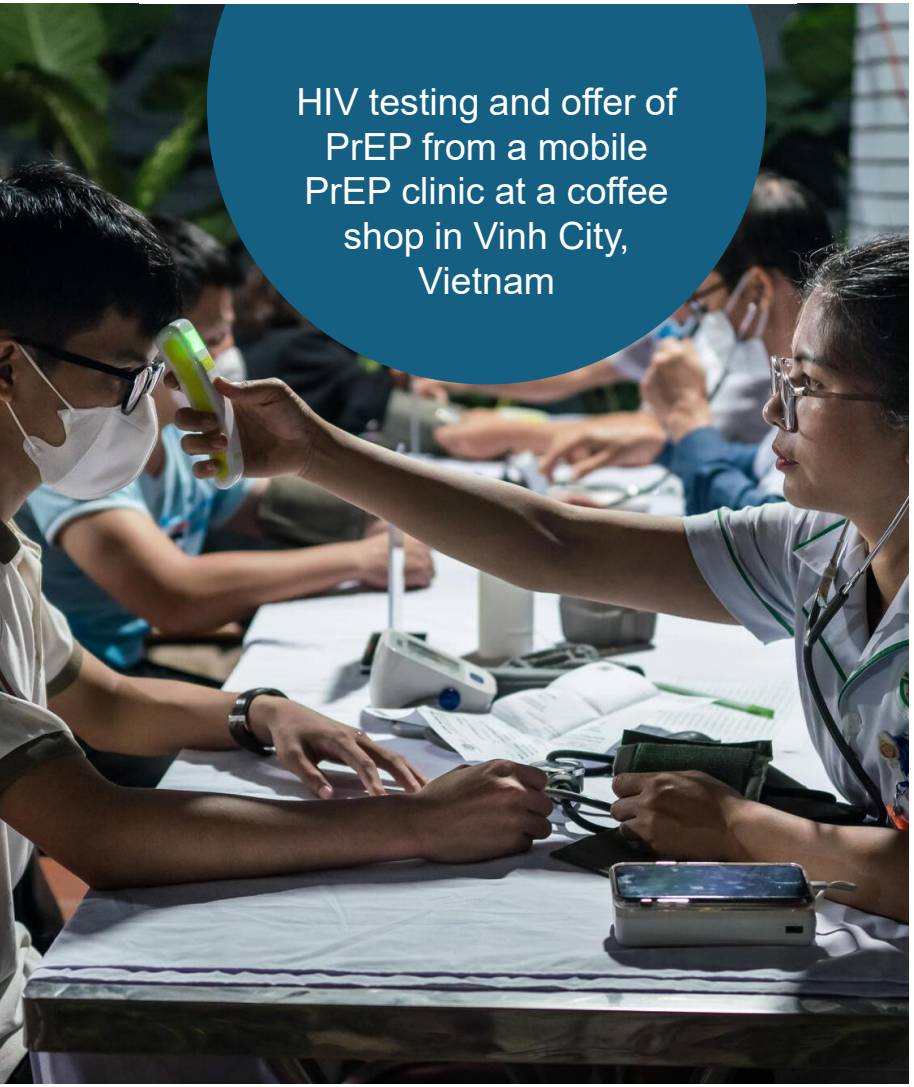
Vindi Singh

Senior HIV Advisor

Global Fund Strategy 2023-2028: END AIDS, accelerate access and use of key products for prevention, testing and treatment

1. Accelerate access to and effective use of precision combination prevention, with behavioral, biomedical, and structural components tailored to the needs of populations at high risk of HIV infection, especially KVP
    - Close gaps in HIV prevention coverage
    - **Accelerate access to and use of new HIV prevention options**
    - Evolve and expand the range of platforms for access to and delivery of people-centered HIV prevention
2. Provide quality, people-centered diagnosis, treatment and care, to improve well-being for PLHIV, prevent premature mortality and eliminate HIV transmission
    - Optimize diagnostic pathways
    - Differentiate and scale up quality HIV treatment services
    - Integrate services to prevent, identify, and treat advanced HIV disease, comorbidities, and coinfections
    - Evolve care pathways to strengthen therapeutic alliances between the people in care and the health and community systems
    - **Accelerate the introduction of diagnostics, therapeutics, technologies, and service delivery innovations**

The Global Fund current grant cycle 7 HIV support to 104 countries



HIV testing and offer of PrEP from a mobile PrEP clinic at a coffee shop in Vinh City, Vietnam

The Global Fund partnership supports

- national programs to provide and scale up **life-saving HIV prevention, testing and treatment services**
- procuring **lifesaving drugs and commodities at competitive prices to** increase access
- rapid introduction of **innovative HIV prevention options** such as **long-acting PrEP and self-tests** through private sector partnerships
- **triple elimination of vertical transmission** of HIV, syphilis and hepatitis B through integrated MNCH/SRH services
- innovative **integrated care models** to support country-led programs and sustainability

Key Results

In countries where the Global Fund invests:

25.6M

People were on **antiretroviral therapy for HIV** in 2024

12.3M

People were **reached with HIV prevention services** in 2024

1.4M

People **received antiretroviral pre-exposure prophylaxis (PrEP)** in 2024.

74%

Of people **living with HIV had a suppressed viral load**.

46.6M

HIV tests were taken (including 11.7 million by priority and key populations).

648K

Mothers living with HIV received medicine to keep them alive and prevent transmitting HIV to their babies in 2024.

772K

Voluntary medical male circumcisions were conducted for HIV prevention in 2024.

Pharmaceutical Products for prevention and treatment

HIV Prevention	HIV Treatment, Advanced HIV Disease and Coinfections
Expand choice, enable self-care, people centered approach	Achieve **early and sustained viral suppression and reduce mortality**

• Pre-exposure prophylaxis options:
  • daily oral meds
  • injectables including lenacapavir
  • new products in development
	• Pediatric ARV formulations
	  • pediatric dolutegravir,
	  • pediatric abacavir/lamuvidine/dolutegravir
	  • pediatric darunavir/ritonavir
	• Newly included regimens in WHO 2025 guidelines
	  • dual therapy such as dolutegravir/lamuvidine and cabotegravir/rilpivirine
	• ARV products in the pipeline
	  • Injectables, long-acting formulations, etc
	• TB preventive treatment
	  • rifapentine/isoniazid (3 month and 1 month course)
	• Treatment options for co-infections and advanced HIV disease

WHO-recommended Antimalarial medicines

Andrea Bosman

Team Lead, Malaria and NTD Case Management and Chemoprevention

WHO-recommended antimalarial medicines

Global Fund Supplier Consultation
March 4th, 2026

Presented by
Dr Andrea Bosman, Team Lead,
Malaria and NTD Case Management and Chemoprevention
email: bosmana@who.int

Malaria and Neglected Tropical Diseases (MNT)

World Health Organization

Key antimalarial interventions & strategies

Prevention

- Insecticide-treated mosquito nets
- Indoor Residual Spraying
- Larviciding

Preventive Chemotherapy

- IPT in pregnancy (IPTp)
- Perennial Malaria Chemoprevention
- Seasonal Malaria Chemoprevention
- IPT in school children
- Post discharge malaria chemoprevention
- Mass Drug Administration

Malaria vaccine

Diagnosis & Treatment

- Parasite based diagnosis
  - Microscopy
  - Rapid Diagnostic Tests
- Uncomplicated Malaria
  - Artemisinin-based combination therapies (ACTs)
- Severe Malaria
  - Artesunate

Case management service delivery areas:

- *Health facilities*
- *Community Case Management*
- *Private sector*

Interventions deploying antimalaria medicines

Surveillance, M & E

- Routine HMIS
- Malaria surveillance and response systems
- Household surveys
- Health Facility Surveys

Strengthening health systems in endemic countries

Malaria remains a serious global health challenge

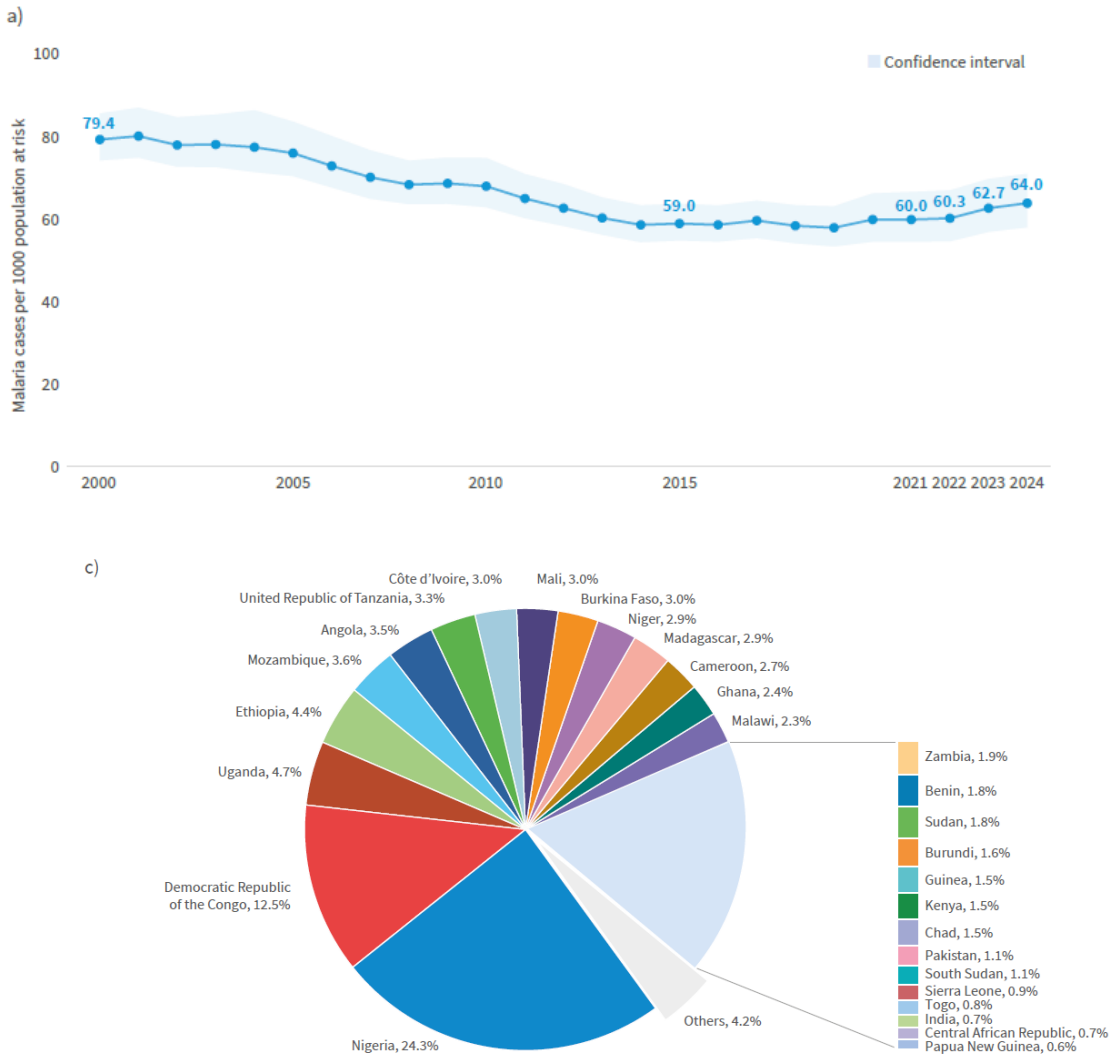
- The period 2023–2024 saw an increase of 9M cases, with 94% of cases in the WHO African Region.
  - **282M cases in 2024**
  - 273M cases in 2023

- Since 2015, case incidence (adjusted for population growth) has risen from 59 to 64 cases per 1000 at risk.

- **Increase in case was largely driven by trends in a limited number of countries** including Ethiopia (+2.9 million), Madagascar (+1.9 million) and Yemen (+378 000)

- Factors contributing to the increase included technical, systemic, environmental, and financial challenges, including weak service delivery and surveillance, conflict and environmental disruptions, some biological threats, social inequities, and funding shortfalls

Fig. 2.3. Global trends in a) malaria case incidence (cases per 1000 population at risk) and b) mortality rate (deaths per 100 000 population at risk), 2000–2024; and c) distribution of malaria cases and d) deaths, by country, 2024 *Source: WHO estimates.*



Case management for children under five has seen improvements

- Effective malaria diagnosis and treatment remain critical to reducing disease burden and improve clinical outcomes
- In 2024, **NMPs distributed 395 million RDTs in 2024**, about 48.5 million (14%) more than in 2023
- **Improved case management** across 21 sub-Saharan African countries
  - Increase in diagnosis with the proportion of febrile children taken to a health provider and received a diagnosis from 30% in 2005-11 to 47% in 2017–24
  - Increase in ACT* share of antimalarials

*Artemisinin-based combination therapies (ACTs) are the most effective and widely recommended treatment for uncomplicated malaria – especially for infections caused by *Plasmodium falciparum*, the parasite responsible for most malaria deaths in Africa.

Use of ACTs

(Of the children who reached a health provider and received an antimalarial drug)

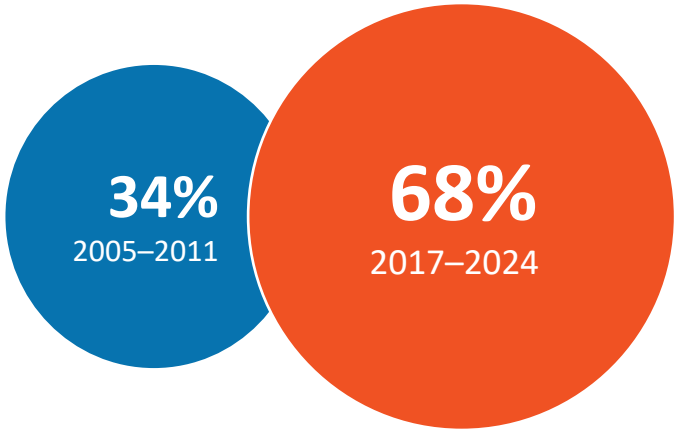
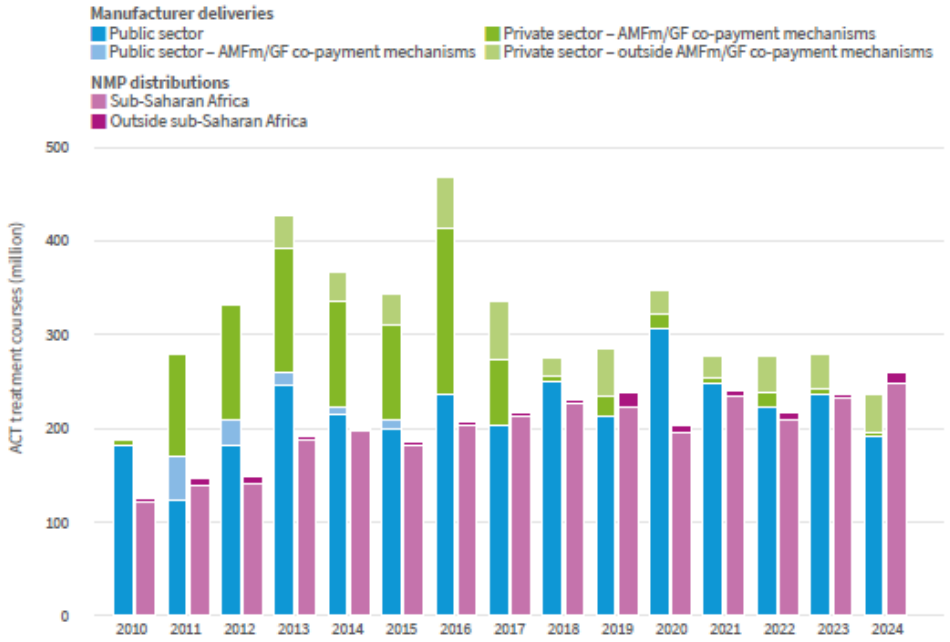


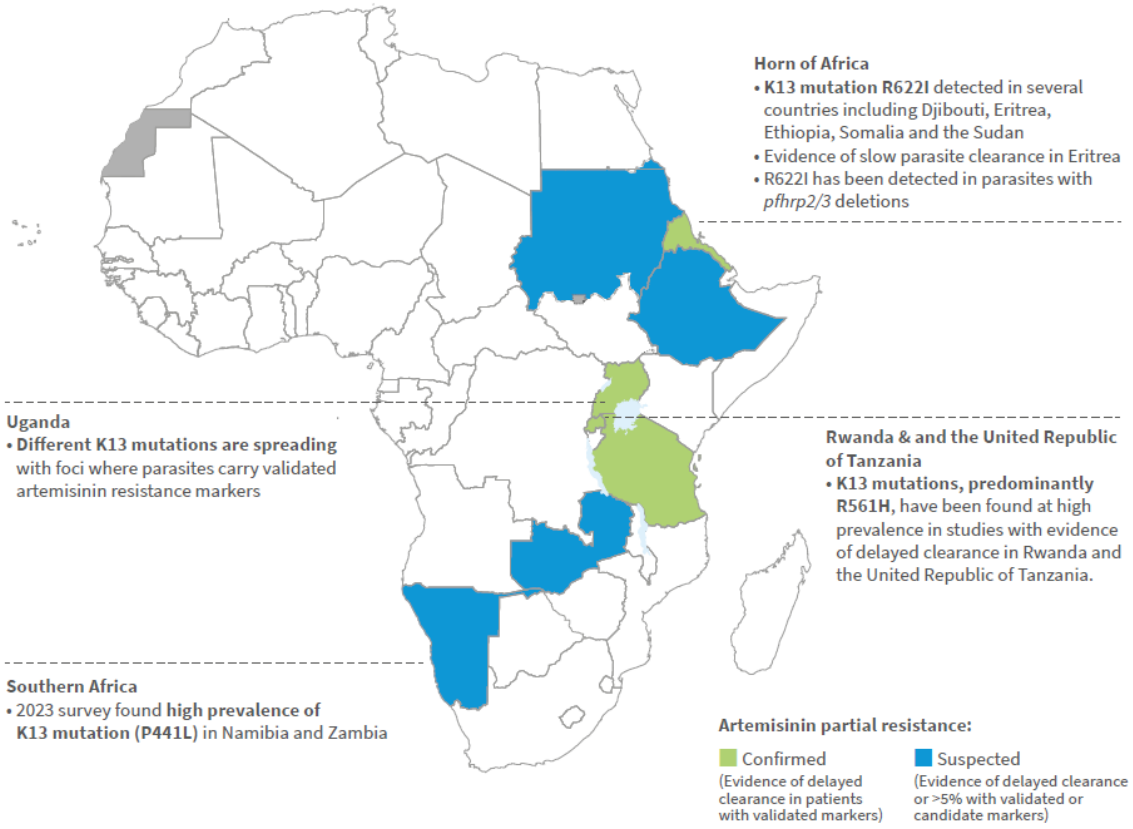
Fig. 5.11. Number of ACT treatment courses delivered by manufacturers and distributed by NMPs to people with malaria, 2010–2024[a,b] *Sources: Companies eligible for procurement by WHO/UNICEF and NMP reports.*



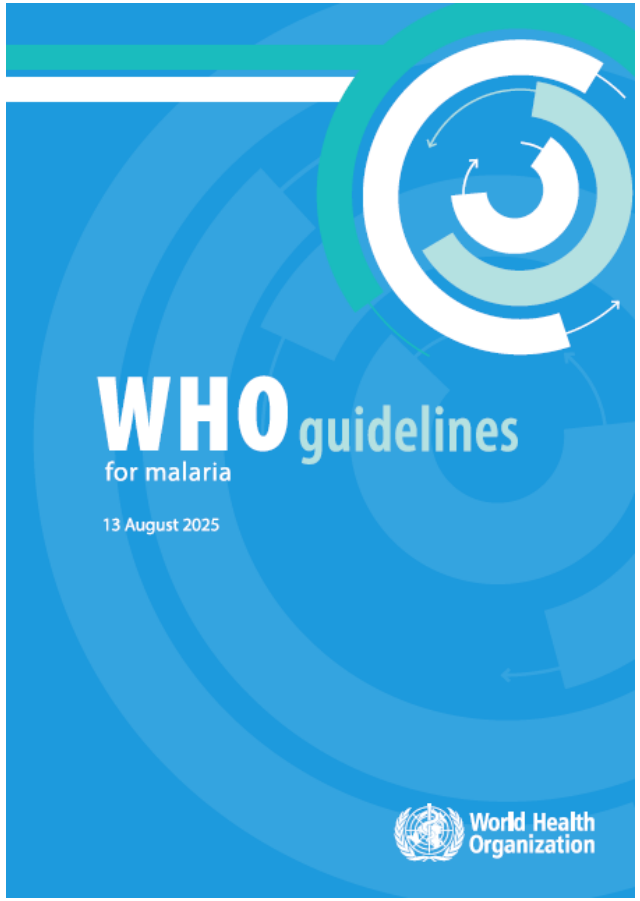
History shows how quickly drug resistance can spread and how devastating its impact can be

- ACTs became the backbone of malaria treatment after failures of chloroquine and sulfadoxine-pyrimethamine
- **Southeast Asia has been the first place where new resistance appears**, including the first reports of artemisinin partial resistance
- **Africa now faces rising risk with many lives at stake**
  - Treatment in Africa relies mainly on artemether-lumefantrine and artesunate-amodiaquine
  - Studies confirm artemisinin partial resistance in four countries and identify suspected resistance in another four
  - In some high-transmission settings (e.g. Uganda), more than half of parasites carry *PfKelch13* mutations associated with resistance

Fig. 7.2. Map of artemisinin partial resistance in Africa



Main malaria prevention and treatment strategies



- WHO Guidelines for Malaria (2021)
  - These consolidated guidelines replaced 2 WHO guidelines the Guidelines for the treatment of malaria, 3rd edition and the Guidelines for malaria vector control.
  - The consolidated WHO Guidelines for malaria include
    - Prevention (vector control, preventive chemotherapies and vaccines)
    - Case management
    - Elimination and prevention of re-introduction
    - Surveillance*
  - As new evidence becomes available, the recommendations will be reviewed and updated, where appropriate, using WHO's transparent and rigorous guideline development process.
- Current 9th update was published on 13 August 2025, and will updated on a continuing basis
- Available online: https://www.who.int/publications/i/item/guidelines-for-malaria

** Not developed following the WHO guidelines development process*

World Health Organization

5.1 Diagnosing malaria (2015)

All cases of suspected malaria should have a **parasitological test** (microscopy or RDT) to confirm the diagnosis. Both microscopy and RDTs should be supported by a quality assurance program.

5.2 Treating uncomplicated malaria

5.2.1 Artemisinin-based combination therapy

Treat children and adults with uncomplicated *P.falciparum* malaria with one of the following ACTs:

- artemether+lumefantrine
- artesunate+amodiaquine
- artesunate+mefloquine
- artesunate+pyronaridine *
- artesunate+sulfadoxine–pyrimethamine *
- dihydroartemisinin+piperaquine

* *not recommended for use in the first trimester of pregnancy*

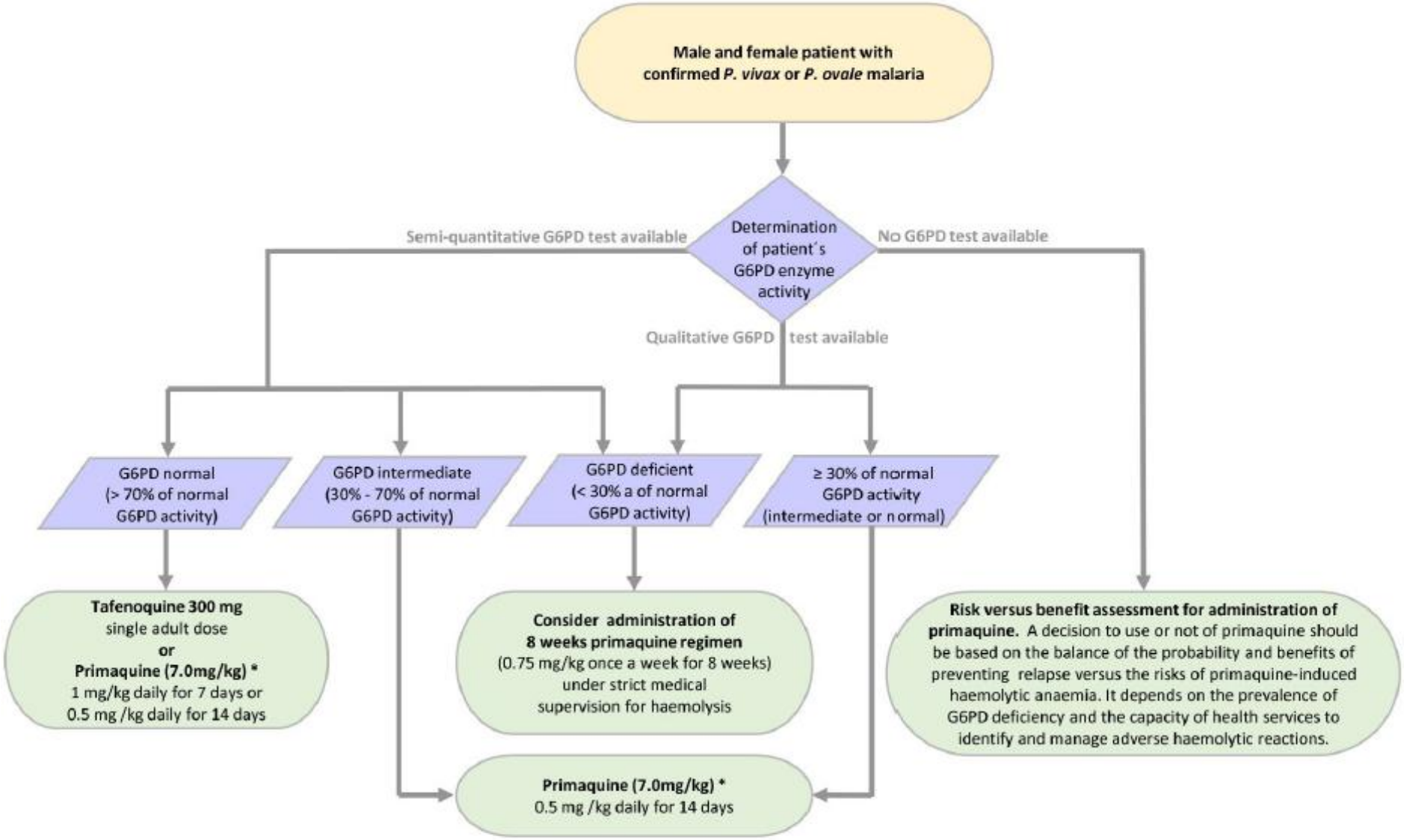
World Health Organization

5.2.1.7 Anti-relapse treatment of *P. vivax* and *P. ovale*

- Tafenoquine is recommended as an alternative to primaquine (3.5 mg/kg total dose) for preventing relapses in patients ≥ 2years of age, who have ≥ 70% G6PD activity and who receive chloroquine treatment.
- Primaquine should be given at a high total dose (7 mg/kg) at 0.5 mg/kg/day for 14 days or 1 mg/kg/day for 7 days for preventing relapses

Quantitative or semi-quantitative determination of G6PD activity must be done to assess if the patient has G6PD activity > 70%, before the administration of tafenoquine or primaquine at 1 mg/kg/day for 7 days

- In people with G6PD deficiency, primaquine base at 0.75 mg/kg once a week for 8 weeks can be given to prevent relapse, under close medical supervision
- In women who are pregnant or breastfeeding, weekly chemoprophylaxis with chloroquine can be given until delivery and breastfeeding are completed, then, on the basis of G6PD status, primaquine can be given to prevent future relapse.



All patients administered primaquine or tafenoquine should be counselled on the risk as well as signs and symptoms of haemolysis; specific attention should be paid to individuals most at risk i.e. all deficient individuals and females with intermediate enzyme activity

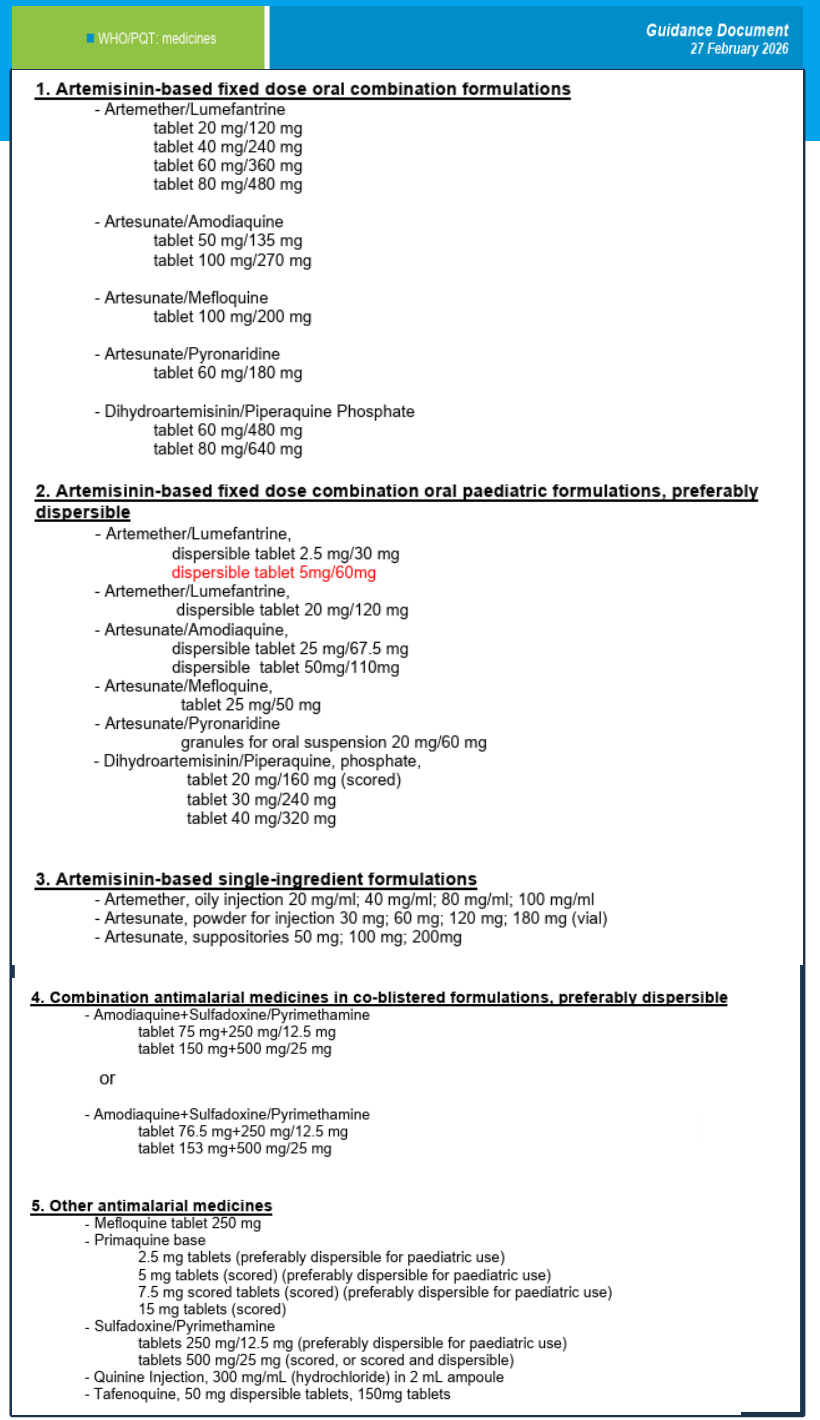
World Health Organization

24th[1] Invitation to Manufacturers of Antimalarial Medicines to Submit an Expression of Interest (EOI) for Product Evaluation to the WHO Prequalification Unit (PQT)

https://extranet.who.int/prequal/sites/default/files/document_files/EOI-MalariaV24_.pdf

List of WHO prequalified medicines

https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products



WHO/PQT: medicines

Guidance Document
27 February 2026

1. Artemisinin-based fixed dose oral combination formulations

- Artemether/Lumefantrine
  - tablet 20 mg/120 mg
  - tablet 40 mg/240 mg
  - tablet 60 mg/360 mg
  - tablet 80 mg/480 mg
- Artesunate/Amodiaquine
  - tablet 50 mg/135 mg
  - tablet 100 mg/270 mg
- Artesunate/Mefloquine
  - tablet 100 mg/200 mg
- Artesunate/Pyronaridine
  - tablet 60 mg/180 mg
- Dihydroartemisinin/Piperaquine Phosphate
  - tablet 60 mg/480 mg
  - tablet 80 mg/640 mg

2. Artemisinin-based fixed dose combination oral paediatric formulations, preferably dispersible

- Artemether/Lumefantrine,
  - dispersible tablet 2.5 mg/30 mg
  - dispersible tablet 5mg/60mg
- Artemether/Lumefantrine,
  - dispersible tablet 20 mg/120 mg
- Artesunate/Amodiaquine,
  - dispersible tablet 25 mg/67.5 mg
  - dispersible tablet 50mg/110mg
- Artesunate/Mefloquine,
  - tablet 25 mg/50 mg
- Artesunate/Pyronaridine
  - granules for oral suspension 20 mg/60 mg
- Dihydroartemisinin/Piperaquine, phosphate,
  - tablet 20 mg/160 mg (scored)
  - tablet 30 mg/240 mg
  - tablet 40 mg/320 mg

3. Artemisinin-based single-ingredient formulations

- Artemether, oily injection 20 mg/ml; 40 mg/ml; 80 mg/ml; 100 mg/ml
- Artesunate, powder for injection 30 mg; 60 mg; 120 mg; 180 mg (vial)
- Artesunate, suppositories 50 mg; 100 mg; 200mg

4. Combination antimalarial medicines in co-blistered formulations, preferably dispersible

- Amodiaquine+Sulfadoxine/Pyrimethamine
  - tablet 75 mg+250 mg/12.5 mg
  - tablet 150 mg+500 mg/25 mg

or

- Amodiaquine+Sulfadoxine/Pyrimethamine
  - tablet 76.5 mg+250 mg/12.5 mg
  - tablet 153 mg+500 mg/25 mg

5. Other antimalarial medicines

- Mefloquine tablet 250 mg
- Primaquine base
  - 2.5 mg tablets (preferably dispersible for paediatric use)
  - 5 mg tablets (scored) (preferably dispersible for paediatric use)
  - 7.5 mg scored tablets (scored) (preferably dispersible for paediatric use)
  - 15 mg tablets (scored)
- Sulfadoxine/Pyrimethamine
  - tablets 250 mg/12.5 mg (preferably dispersible for paediatric use)
  - tablets 500 mg/25 mg (scored, or scored and dispersible)
- Quinine Injection, 300 mg/mL (hydrochloride) in 2 mL ampoule
- Tafenoquine, 50 mg dispersible tablets, 150mg tablets

Thank you
for your attention



World Health Organization

Global Fund ANTM Update

Htin Kyaw Thu

Senior specialist malaria Case Management

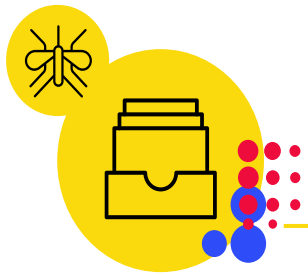
Priorities for malaria case management



Treatment of malaria:

- **Ensure person-centered, uninterrupted access to early diagnosis and effective treatment leveraging all sectors per country context**
- **Addressing biological threats to case management interventions is a priority.**
  - **Antimalarial drug resistance**: strengthen quality case management, protect the efficacy of existing molecules and prepare the introductions of innovative treatments.
- **Case management commodities**
  - **Access to quality-assured ACTs** (WHO-Prequalified, recommended products in line with Global Fund Quality Assurance policies and Procurement policy and/or the Guide to Global Fund Policies on Procurement and Supply Management of Health Products) across sectors, including private sector. Within this foundation**, rational ACT** selection and stewardship.
  - **Single Low-dose Primaquine** with ACTs for *Pf* cases offer additional transmission reduction benefits in line with WHO guidance
  - Introduction of dose-optimized child friendly formulations to reduce the treatment gaps. (e.g., pediatric Primaquine)
  - **Radical Cure for *Plasmodium vivax*** (priority dependent on burden of *Pv* and health systems contexts) – support implementation of radical cure package (Primaquine or Tafenoquine and G6PD testing)
  - **Management of severe malaria** and continuum of care

Priorities for chemoprevention



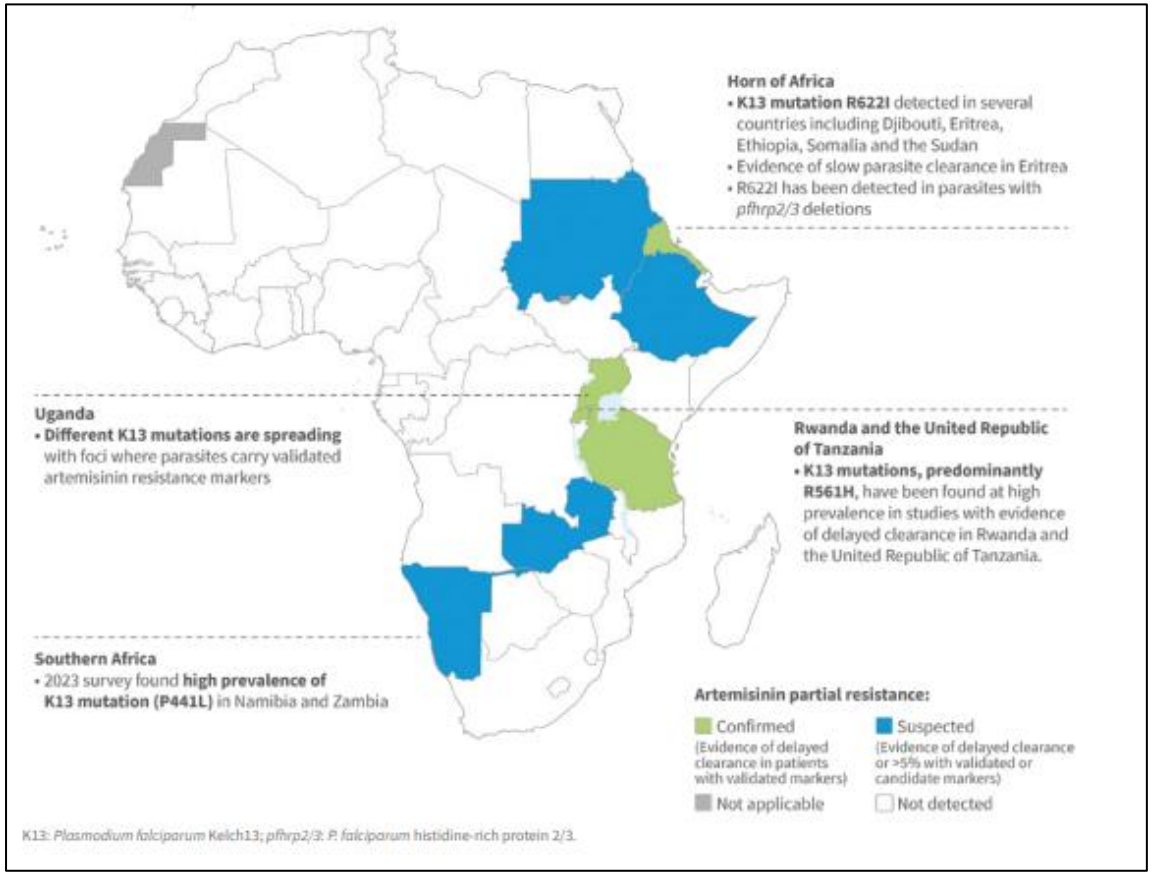
Preventive chemotherapy:

- Subnational tailoring of **Seasonal Malaria Chemoprevention (SMC)**, with priority on high burden, hard to reach areas for children under 5
- **Malaria in pregnancy** – strengthen integration for holistic package of antenatal care services; if have community based Intermittent Preventive Treatment in pregnancy, should be fully embedded in community health worker package
- **Perennial Malaria Chemoprevention** (PMC)
- **Mass Drug Administration (MDA)**for transmission reduction can be supported in the context of intensified elimination efforts targeting all or specific vulnerable populations, noting the need to address barriers to reaching these populations. Prioritizing MDA must be balanced with funding for interventions which have longer-term effects on burden or transmission.

Respond to artemisinin partial and partner drug resistance

The role of diversified antimalarial portfolio

- **Over-reliance on a single ACT** creates long-term vulnerability to resistance.
- WHO Strategy to respond to antimalarial drug resistance in Africa recognizes the need to promote the **availability of a diversified drug portfolio in countries.**
- As countries update national treatment policies and AMDR mitigation strategies, approaches such as Multiple First-Line Therapies are being considered, which will **generate demand for some alternative WHO recommended ACTs.**
- In the context of emerging resistance, a resilient market requires multiple quality-assured ACTs to remain **affordable, and available**.
- Alongside **optimized use of existing ACTs, the newer antimalarials** e.g., first-ever non artemisinin combination therapies and Triple ACTs that are advancing in the development pipeline have important role in our resistance mitigation.



Map of artemisinin-partial resistance in Africa
Ref: World Malaria Report 2025

THE GLOBAL FUND

PAHO

Daniel Rodriguez
Director, Procurement & Supply Management

Martha Suazo
a.i. Unit Chief, Procurement Strategic Fund

PAHO's Regional Revolving Funds



STRONGER TOGETHER

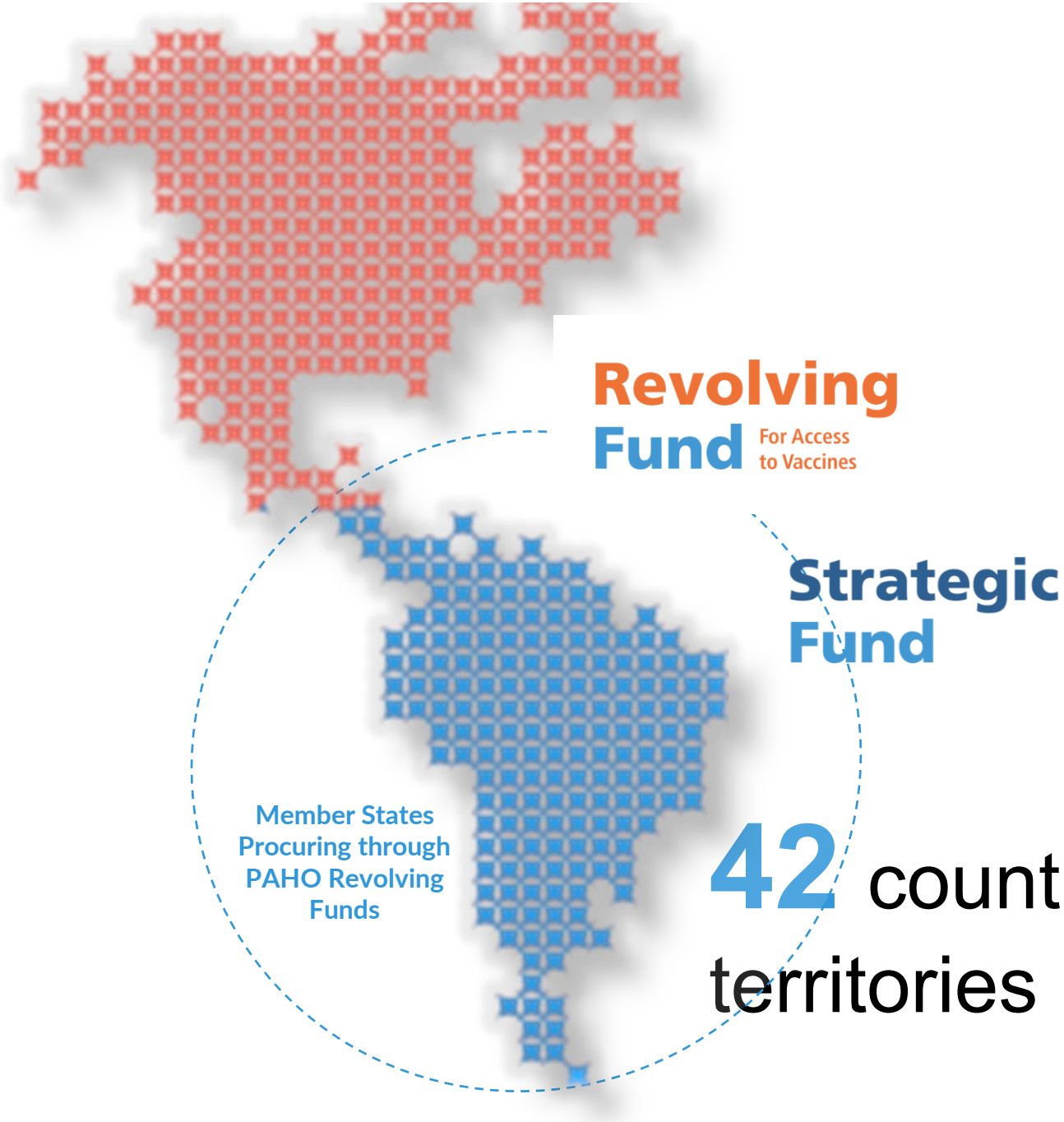
PAHO

Pan American Health Organization

World Health Organization

Americas Region

What are PAHO's Regional Revolving Funds?



The RRFs are **technical cooperation mechanisms** that enable the Americas to equitable access timely quality **vaccines, essential medicines**, and public health supplies.

Through **pooled procurement**, Member States obtain affordable prices and **plan their demand together** to obtain benefits for all plus, **a reliable demand predictability.**

42 countries & territories

Regional Revolving Funds

Regional Revolving Funds Achievements in 2025

42
Countries and territories

27
Health Agencies using the Funds

Up to
180M
People impacted by the Funds in the last biennium

Around
50%
in savings for purchases of vaccines

Around
234M
Vaccine doses

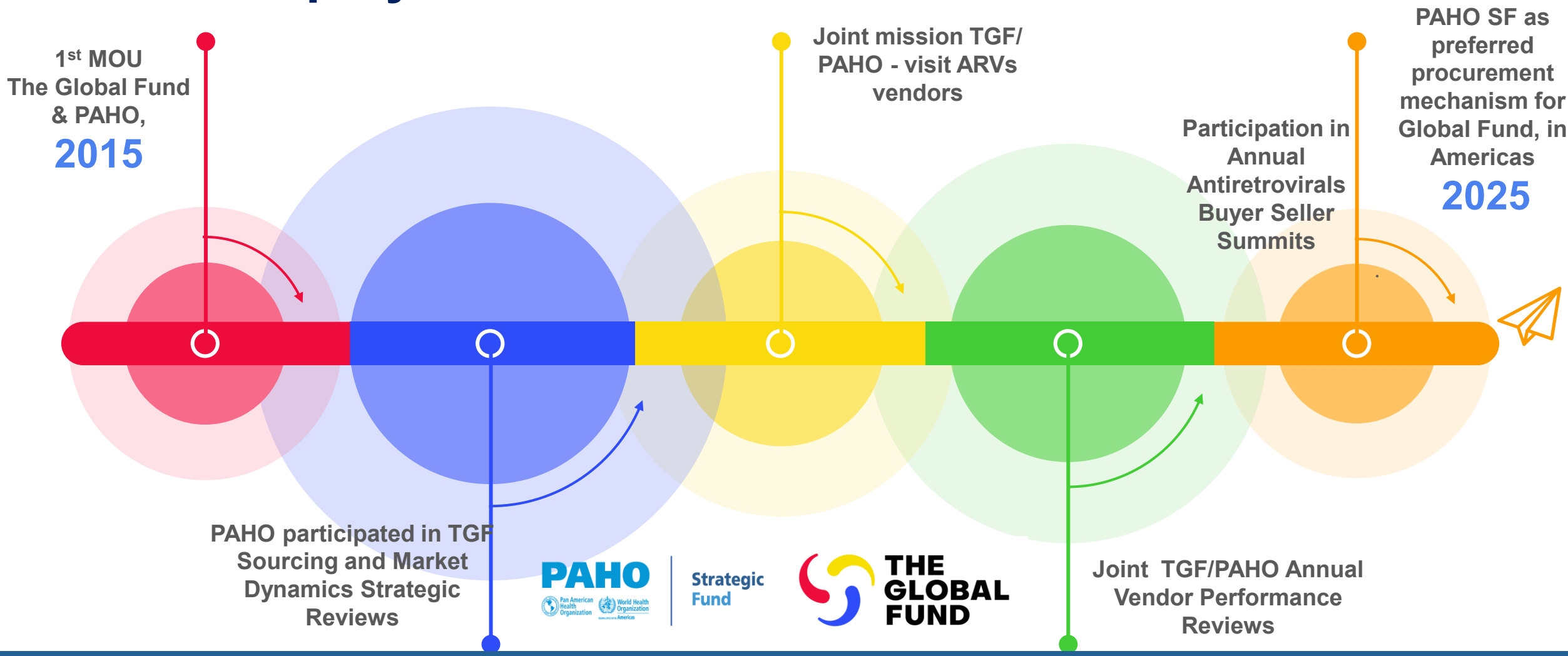
Around
50%
Reduction in prices of key antiretrovirals

Around
90%
Reduction in prices of Oncology and High Cost medicines

+18M
Treatments and diagnostics

Access to **PCV-20 Locally produced**, through the Fund

Leveraging Partnerships to Increase Equity on Health Access





Key Achievements

- ✓ **Expanded access to affordable ARVs at scale**: Approximately **US$250 million in ARVs** procured by PAHO leveraging Global Fund PPM-negotiated terms, outside Global Fund grant financing.

- ✓ **Inclusive reach across the region:** **More than 15 PAHO Member States**, including Small Islands Developing States (SIDS), gained access to quality-assured medicines.

- ✓ **Stronger market outcomes:** Access to multiple WHO-PQ suppliers, **reduced supplier concentration risk**, and procurement timelines comparable to direct PPM purchasing (around 90–120 days).

Why This Partnership Matters?

- **Aligned Market & Sustainable Health Systems Goals:** The Global Fund's goals of affordability, quality, and sustainability are aligned with PAHO's procurement objectives on supporting access, self-financial sustainability & elimination goals.

- **Collaborative Performance Management :** Joint collaborative & transparent work to ensure a continuous supply of ARVs.

- **Complementary strengths leveraged effectively:** The Global Fund's large-scale negotiation power is combined with PAHO's regional reach, payment terms, and relationships with Member States.



Thank you!

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https://www.paho.org/en/doing-business-paho



PAHO
Pan American Health Organization
World Health Organization
Americas Region

Regional Revolving Funds

Q&A

Thank You