

Procurement and NextGen Market Shaping Update

53rd Board Meeting

7 – 9 May 2025, Geneva, Switzerland

Board Information

GF/B53/05

Executive Summary

Context

1. The Board is receiving this procurement and NextGen Market Shaping update as part of the annual reporting requirement for these critical activities contributing to Global Fund's mission and strategic objectives. The Global Fund continues to drive value for money through its procurement activities, focusing on effectiveness, efficiency and stewardship.
2. The Global Fund leverages its procurement scale and operating model and, through its NextGen Market Shaping approach, drives equitable access to affordable and quality assured health products and innovations by breaking down access barriers, leveraging partnerships and communities, resulting in greater health outcomes and contributing to improved health security. Key interventions include accelerating new product introductions, building capacity for regional manufacturing and procurement, and promoting sustainable procurement and supply chains.
3. Given ongoing challenges linked to the evolving geopolitical context and changing public health landscape, the Global Fund's procurement and NextGen Market Shaping approach needs to be fully leveraged to respond to key challenges and opportunities to ensure continuation of the live saving mission, accelerate progress, and stabilize and sustain key markets needed to end the three diseases.
4. The updated Procurement and Quality Assurance (QA) Policies approved by the Board in 2023/2024 were timely and enabled the Secretariat to respond better to the evolving context through implementation of the Policies. Particularly, the roll-out of the operational framework of the Procurement Policy will be leveraged to support countries with procurement interventions. It is noted that countries' capacity to implement the QA policies needs to be further monitored, and additional time would be required.

Questions addressed in this slide deck

1. What was the status of 2024 procurement activity performed and how is the Secretariat responding to current challenges?
2. What were the main NextGen Market Shaping achievements in 2024 and what is the status of ongoing priorities and the outlook?
3. What is the status of operationalization of the Procurement and Quality Assurance Policies?

Input Received – Strategy Committee (SC) discussions (SC22, SC23, SC24, SC26, SC27), Audit and Finance Committee discussion (AFC24, AFC27), informal AFC Call on 20 September 2024 and Board discussions (B50, B51).



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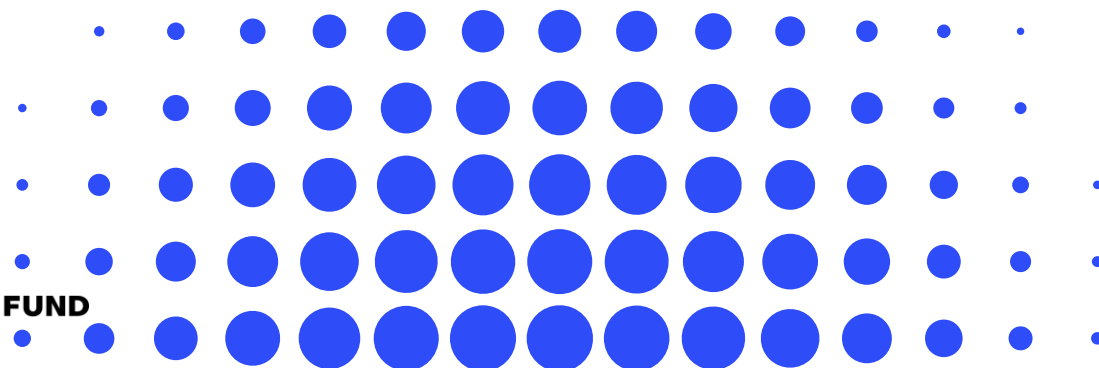
A Procurement Overview and Update

- 1** Procurement Report Summary for 2024
- 2** Responding to the evolving context

B NextGen Market Shaping Progress

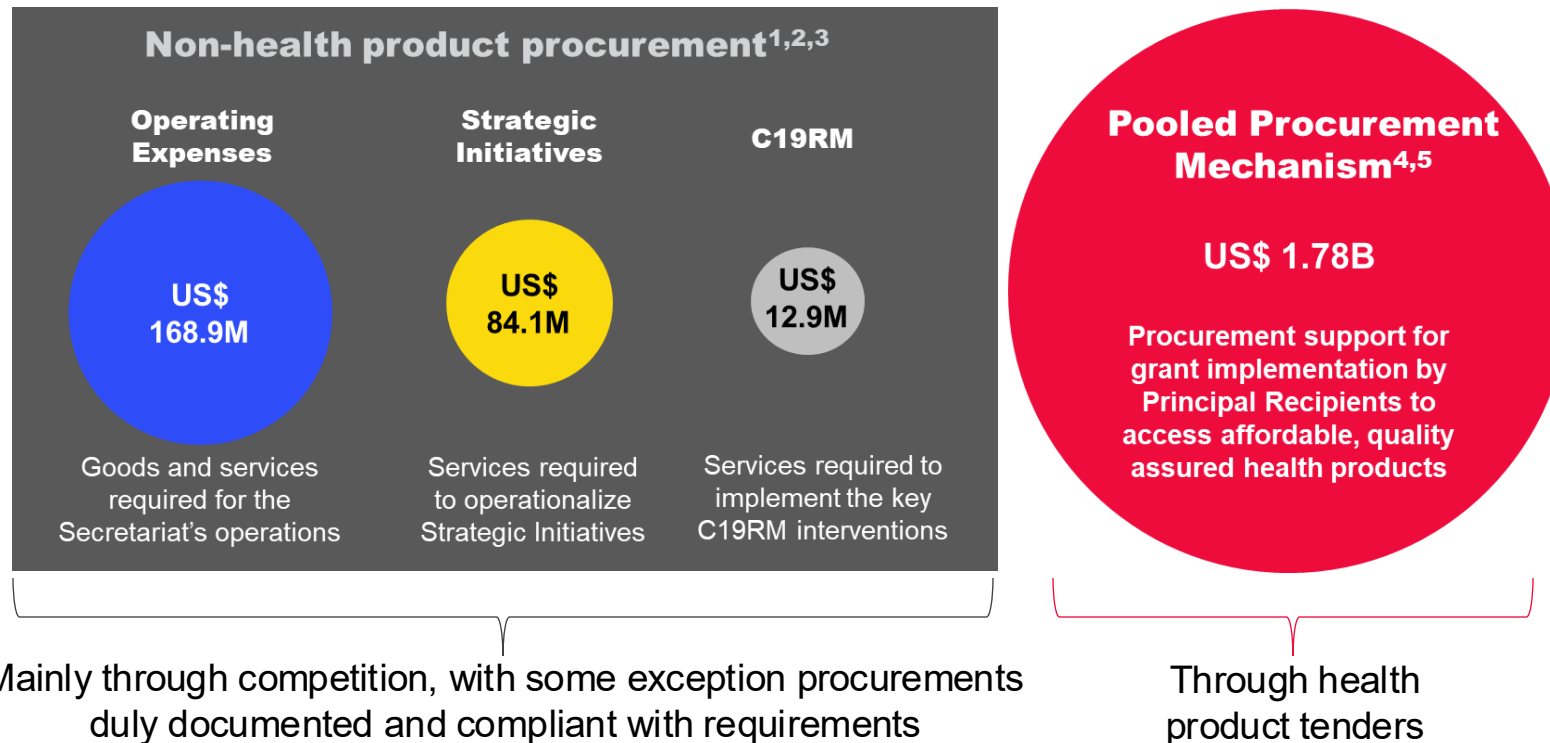
- 1** Overview of 2024 NextGen Market Shaping Achievements
- 2** Ongoing NextGen Market Shaping Priorities and Outlook

C Procurement and Quality Assurance Policy Implementation



The Global Fund continued to drive value for money through its procurement activities, focusing on effectiveness, efficiency and stewardship

In 2024, the total procurement value managed by the Secretariat amounted to ~US\$2Bn



- 1 A key accomplishment in 2024 was approval of the updated Procurement Policy in April.
- 2 This report is the first Annual Procurement Update, providing a comprehensive overview on the Secretariat's procurement activities and compliance with the Procurement Policy.
- 3 It includes information across the procurement value chain by category, procurement method, collaborative procurement, exception reporting and trade-offs, and more.
- 4 This approach going forward provides insight to support the AFC and Board in fulfilling their oversight functions.
- 5 This 2025 annual procurement update is based on existing rules and regulations. The next annual procurement update in Q1 2026 will be reported on the updated procurement rules and regulation set out in the operational framework of the updated Procurement Policy that is under implementation.

¹ Procurement value relates to the value of Purchase Orders issued in 2024. Data downloaded on 25 February 2025 using spot rates for non-US\$ currencies.

² This is exclusive of co-financing, which had a 2024 procurement value of US\$ 4.8M, almost exclusively for Human Resource services and Professional Services.

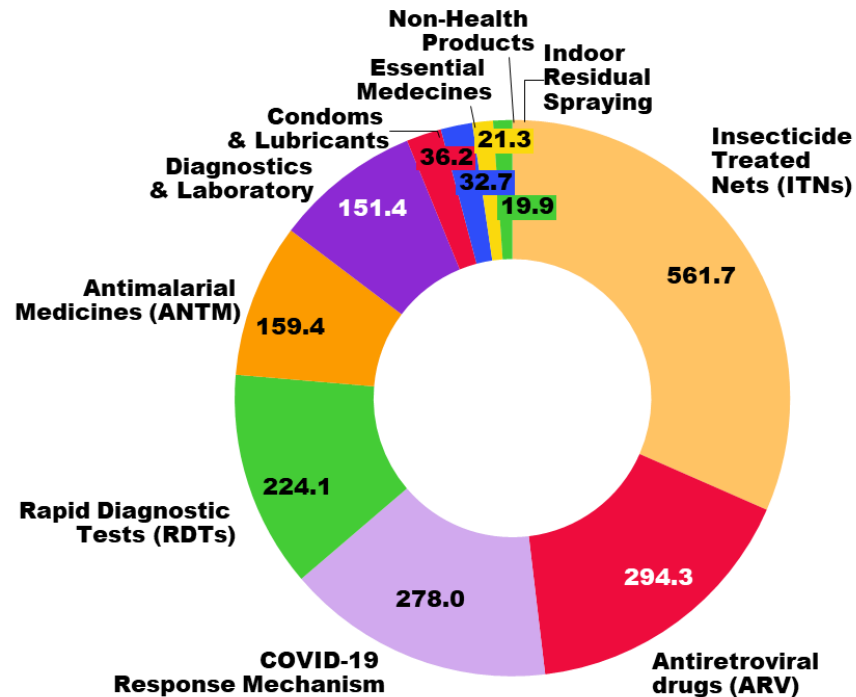
³ Additional information provided in Section A of the Pre-Read.

⁴ Whilst PPM/wambo.org is the largest procurement channel for health products using grant funds accounting typically for 50-60% health product procurement depending on product category, other procurement channels include national procurement and, procuring through other international and regional procurement mechanisms, such as UNDP (primarily when PR), GDF, UNICEF, and PAHO.

⁵ Value not inclusive of revisions on purchase orders issued in prior years. Includes product and procurement and supply management costs to country.

In 2024, US\$ 1.78Bn in approved purchase orders was for health products ordered by Principal Recipients through PPM/wambo.org¹

Procurement by Category
(in US\$ million, Pooled Procurement Mechanism)



Global Fund's Pooled Procurement Mechanism / wambo.org

Through the mechanism, Principal Recipients can place orders for the health products they need to implement their programs. Eligible buyers can also place orders for health products with non-Global Fund finances; that data is reported separately (see Section C).

Of the US\$ 1.78bn value of grant-funded health product procurements in 2024, 70% was transacted through Global Fund-managed long-term performance-based framework agreements with suppliers. The remainder was managed by Procurement Services Agents and partner organizations, in line with the Procurement Policy.

PPM procurement consistently adheres to the core principles of the Policy.

- 1. Value for Money:** Pooled procurement provides rolling demand forecasting, enabling better production planning, optimizing upstream supply chain management, resulting in overhead efficiency and returns on investments.
- 2. Effective Competition:** Suppliers participate in competitive tenders and are incentivized to excel in performance and innovation, ensuring efficiency gains that ultimately benefit the people served.
- 3. Fairness, Impartiality, and Integrity:** Transparent and consistent quality requirements create a level playing field, encouraging suppliers to invest in quality management and continuous improvement.
- 4. Client centricity:** Products made available are aligned to clinical recommendation for intended use and efficacy, meeting national requirements and end-user needs.
- 5. Sustainable Procurement:** PPM guarantees timely payment, fosters open competition among all eligible suppliers, and promotes long-term sustainability in the market.
- 6. Best interest of the Global Fund:** Affordable, quality assured health products are essential for ending the three diseases.

¹ Value of confirmed purchase orders in 2024; value not inclusive of revisions on purchase orders issued in prior years.

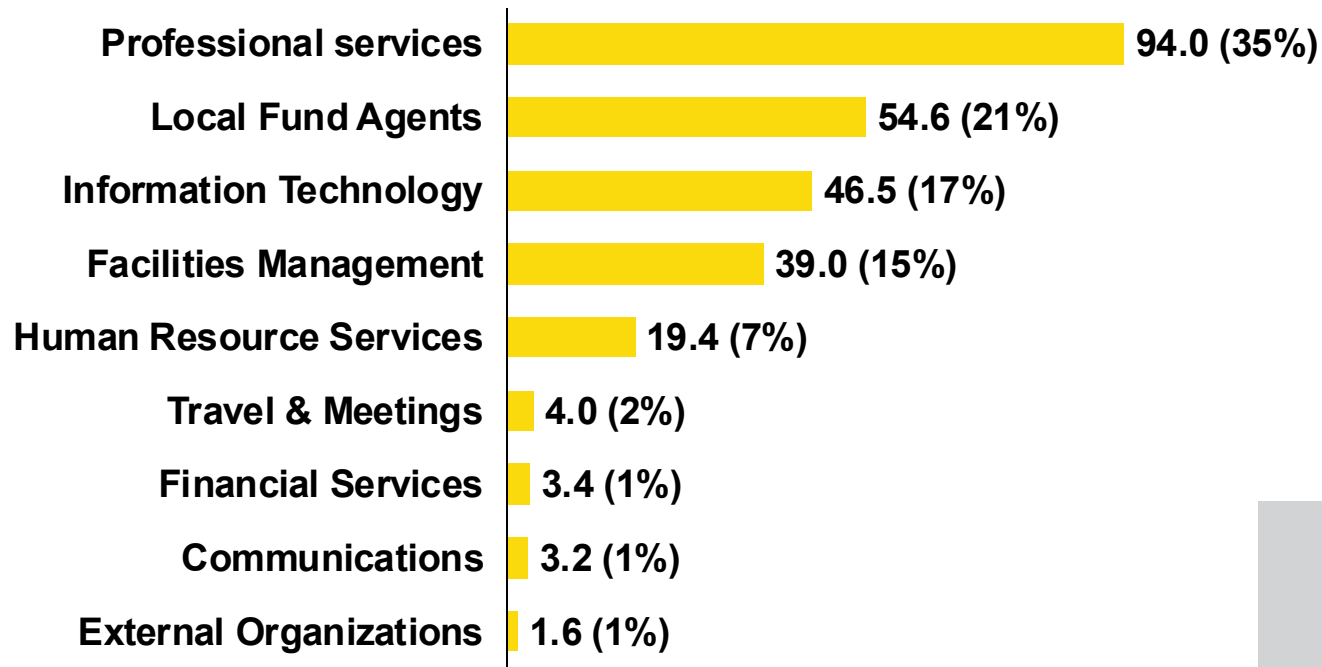
Includes product and procurement and supply management costs to country.

Note that this is exclusive of most TB volumes (i.e., all TB medicines and most TB diagnostics), which are procured through the Stop TB Partnership's Global Drug Facility (GDF).

In 2024, procurement of goods and services through OPEX, SI and C19RM amounted to US\$ 265.8M^{1,2,3}

In 2024 the top 4 categories represent 88% of the procurement

Procurement by Category in US\$ million in 2024^{1,2,3,4,5}



US\$ 265.8M total procurement value

Categories and scale of procurement largely in line with the Financial Forecast.

1. All procurements are transacted through purchases orders in the Enterprise Resource Planning system with integrated workflow and approvals, with due consideration of segregation of duties.
2. Ongoing efforts resulted in increased numbers of long-term agreements to ensure value for money.
3. Further enhancements to drive procurement efficiency and stewardship are planned with the operationalization of the updated procurement policy. See Annex 1 for more details.

Additional insight into select categories

- **Professional services:** Technical assistance and strategic support, such as laboratory systems, supply chain and others, independent evaluation and learning, strategic project management and advisory, and others
- **LFA:** Professional services and LFA travel
- **IT:** IT consultants, office infrastructure, Software as a Service, and others
- **Facilities Management:** Rent, service providers and others; incl. catering
- **HR Services:** Temporary workforce, recruitment services and others
- **Travel & meetings:** Venue hire, security services, facilitators, transport and accommodation for Board and non-staff – excludes travel for staff
- **Financial Services:** Professional fees for audits, including OIG audits
- **External organizations:** Services related to TRP, IEP, CRG Honorarium

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³ Excludes Co-financing, which had a 2024 procurement value of US\$ 4.8M, 95% of which was for HR and professional services.

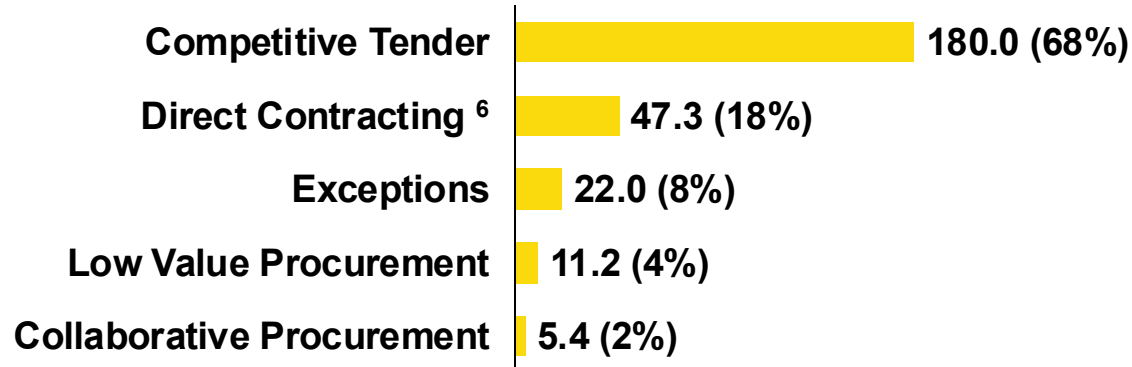
⁴ For clarity, exclusive of: salaries, disbursements to CCMs, Board Constituency Funding, Purchase Orders issued for travel by the travel services agent, health product procurement and depreciation of assets.

⁵ Some totals may not add up due to rounding.

Competitive tenders remain the main procurement method used in 2024 for the Global Fund [OPEX, SI, C19RM]

Different procurement methods are necessary to balance competition, efficiency, and risk management, ensuring the best value for money while meeting operational needs.

Procurement by Method in US\$ million in 2024^{1,2,3,4,5}



US\$ 265.8M total procurement value

Competitive tender is Global Fund's default procurement method, with overall improvement through better procurement planning

1. Stringent criteria are defined and complied when direct contracting modality is applied. Direct contracting is used when there is a case for sole source, i.e., only one suitable supplier or Board-mandated procurement.
2. Exception procurements undergo a due-diligence review and approval process and are well documented and monitored. Exceptions mostly relate to contract extensions for service continuation. [See Annex 1 for examples.]

With the implementation of the operational framework of the procurement policy, we aim to further strengthen the stewardship and compliance of the Secretariat's procurement.

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⁶ Direct Contracting also includes Board-mandated procurement, including Global Health Campus rent, Technical Review Panel and Independent Review Panel.

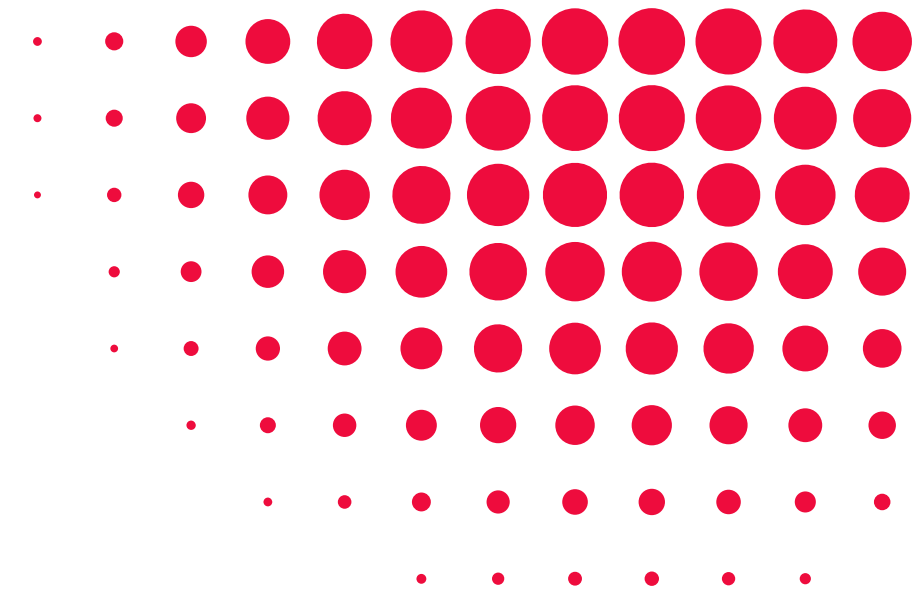
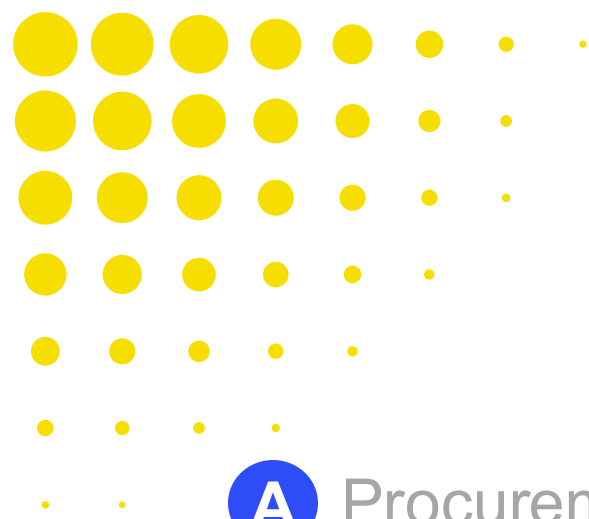
The Global Fund has been implementing a range of activities to improve efficiency while ensuring compliance

Driving Efficiency & Effectiveness through Automation, Visibility and Streamlined Processes

- 1. Automation & Digitization:** Manual, time-consuming processes, analysis and approvals have been integrated in the system for digitization and automation. This has results in reducing approval time from 10 hours to 1 hour; reduction of non-digitized processes and thereby addressing inefficiencies in nearly 40% of procurement volume, improving data quality, reporting accuracy, and compliance.
- 2. Process Streamlining:** Reduction in the number of approvals without compromising compliance, minimizing duplication, and embedding requirements directly into the system; implementation of automated approval workflows and contract digitization has reduced errors from ~7% to 0%.
- 3. Enhanced Visibility & Audit Trails:** Full end-to-end (E2E) visibility of the procurement process, including purchase requisitions (PR), purchase orders (PO), and invoicing, ensuring transparency.
- 4. Error Reduction: Training & Knowledge Sharing:** Establishment of an eLearning platform and a new procurement Engage page, leading to increased engagement and training completion.
- 5. Procurement Performance Monitoring:** Introduction of performance indicators, tracking tools, and exception monitoring, including lead time indicators, vendor management improvements, and risk mitigation strategies.
- 6. Stakeholder Engagement & Continuous Improvement:** Regular surveys, hackathons and process reviews to align procurement with organizational needs.

Driving stewardship and compliance through the operational framework

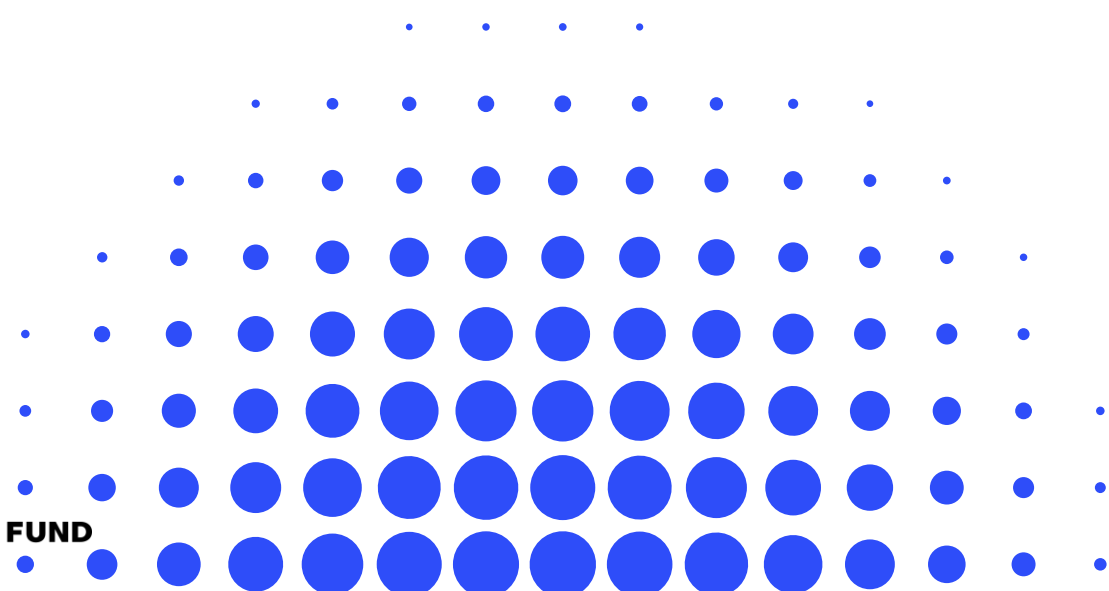
- 1. Clear Roles & Responsibilities:** Defined procurement roles with segregated duties to prevent conflicts of interest and ensure accountability.
- 2. Integrity Due Diligence:** Essential and enhanced integrity checks on suppliers to mitigate operational, reputational, and financial risks.
- 3. Transparent & Competitive Sourcing:** Open and limited competition methods with well-documented justification for exceptions.
- 4. Sustainable Procurement:** Integration of sustainability principles.
- 5. Supplier Performance Management:** Continuous monitoring, quarterly business reviews, and structured performance evaluation.
- 6. Procurement Review & Oversight:** Multi-tiered review mechanisms, including Procurement Review Committees, ensuring compliance with policies and risk assessment.



A Procurement Overview and Update

1 Procurement Reporting for 2024

2 Responding to the evolving context



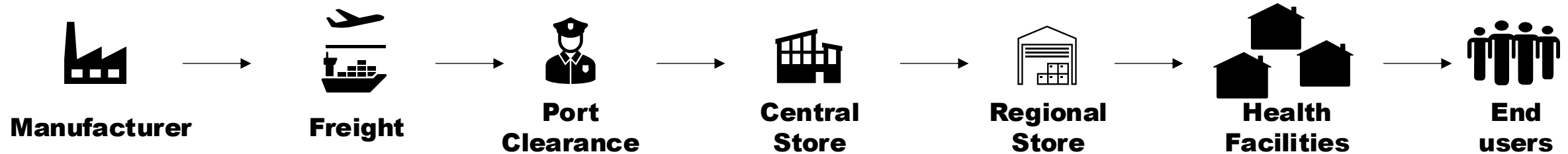
Evolving geopolitical context, changing public health landscape and tariffs are impacting procurement value chains

Evolving business needs	Existing procurement plans may need to be adapted by the Global Fund and countries to respond to emerging needs.
Lack of information and data	Limited visibility on dynamic situation, including on downstream supply chains due to partners stopping work, results in lack of insight to optimally respond.
Market response	Uncertainty of funded demand and rising commodity and production costs causing market disruptions, with risks of short-term supply shocks and price volatility, and longer-term market sustainability issues.
Ability to plan and adapt	Dynamic situation requires rapid, efficient procurement processes and decision-making, while facing increased risks of mis-management and quality concerns in a highly volatile environment.
Procurement support	Need to rapidly adapt to the evolving needs and support countries with debottlenecking in-country supply chain capacities and ability to access affordable and quality assured health products.

Key risks need to be addressed to minimize disruption and ensure value for money as the Global Fund continues its life-saving mission and support to countries

Elevated concerns on supply chain disruptions may impact access and delivery of life saving health products – from manufacturers to patients

Addressing these challenges will require agility, adaptation and strong collaboration across partners



Near-Term Implications

1. Access challenges: Disrupted distribution networks leading to over-stock / stock-outs and additional logistic costs and waste
2. Visibility and Information: Impact of partners stopping work leading to lack of visibility on downstream supply chain, resulting in sub-optimal response and program adaptation
3. Supply shocks: Risk for key low volume products, cash flow issues, price volatility, and quality concerns, chaos and confusion around evolving tariffs may cause shipment delays, misclassifications at customs and temporary bottlenecks
4. Currency volatility and price adjustments: Exchange rate fluctuations may increase pricing uncertainty, especially in USD-sensitive contracts
5. Shipping cost swings: Drop in global shipping demand may increase container availability with short-term price drops, but as products get stuck, container shortages could cause price spikes

Medium/Long-Term Implications

1. Supply chain friction: Customs authorities in impacted countries might struggle to classify products and apply the right duties or release shipments quickly, leading to delayed deliveries with additional costs and operational issues
2. Inflation and rising cost of goods: Foreign exchange volatility and inflation may affect unit costs across categories, particularly those with long value chains
3. Possible market failure: e.g., low volume products or unpredictable demand, such as pediatric antiretroviral medicines
4. Possible market exit/consolidation: suppliers divest critical markets leading to lack of competition, market exit, and reduced investment in innovation
5. Potential impact on program and disease outcomes: availability and affordability impact access, procurement, supply and delivery of life saving health products

Progress made in 2024 has positioned the Global Fund to respond effectively and agilely to the evolving context to mitigate upstream and downstream risks

- 1 **Accelerated Procurement Policy Implementation:** The Procurement Manual was launched on April 7th to deliver efficient Procurement Policy rollout and accelerate impact of updated policy provisions, such as relating to emergency measures
- 2 **Enhanced country coordination:** Work with countries to improve visibility and foster joint planning to enable optimal response, mitigate risk of overstock/out-of-stocks, wastage, and disrupted services, to avert additional costs to Global Fund and countries
- 3 **Leverage PPM/wambo.org:** As countries increase domestic spending, leverage PPM long-term agreements and PPM/wambo.org's non-grant channel to ensure value for money, quality-assurance and avoid fragmentation which could drive higher costs
- 4 **Leverage NextGen Market Shaping:** Marketing shaping tools to be considered to stabilize key markets and avert risk of market failures that could lead to devastating consequences, e.g., pediatric treatments and prevention.
- 5 **Prioritization and partnerships:** Prioritization focusing on critical life-saving interventions and complementary partnership efforts to sustain momentum on innovation and access to new, optimal tools required to end the three diseases

The Secretariat is monitoring the situation closely, assessing risks and evolving mitigation measures as more information becomes available.

The aim is to ensure Global Fund continues its life-saving mission and support to countries



B NextGen Market Shaping Progress

- 1** Overview of 2024 NextGen Market Shaping Achievements
- 2** Ongoing NextGen Market Shaping Priorities and Outlook

In 2024 the Global Fund continued to leverage its pooled procurement mechanism (PPM), driving efficiency and improve access to quality assured health products¹

Implementation of long-term framework agreements and pooling demand through wambo.org continues to deliver **more optimal health products for less in a budget-constrained environment**²

634 Principal Recipient users from **125 organizations** in **81 countries** placed orders through PPM/wambo.org⁵

1,668 purchase orders placed with a total value of **US\$1.78 bn** through PPM/wambo.org⁷ [the largest annual throughput to date except for 2021 during the COVID-19 pandemic]

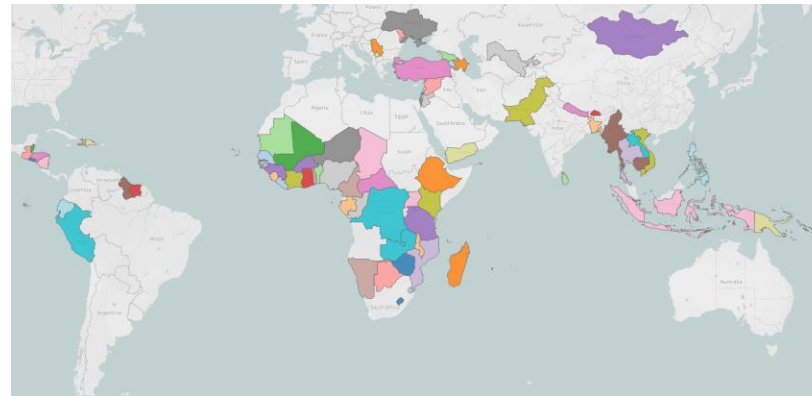
HIV
4.7 M people on 1st line ARV treatment
Improved coverage versus the comparable year of Grant Cycle (GC) 6 (2021). **35% lower cost through** implementing 2022 tender outcomes.³

Malaria

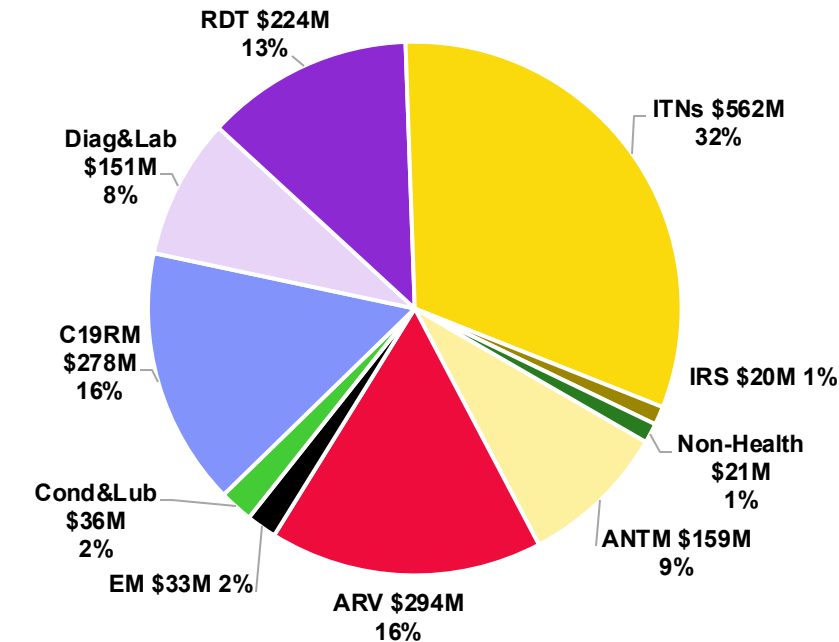
120 M treatment courses ACTs
26% more treatments than the comparable year of GC6 (2021) with **8% price reductions**.⁴

Malaria

174 M Nets
38% more nets than the comparable year of GC6 (2021). Most nets ordered were the **more effective chlorfenapyr-based dual active ingredient** nets.



- More than 4,000 shipments delivered in 2024
- **6 countries** also procured **US\$ 22.5 M** products using **non-grant funds**, including towards their co-financing commitments.⁶
- Cumulatively, **28 countries** have procured **~ US\$ 100 million** products since 2017 with non-grant funds



- ITNs: Insecticide-treated bed nets
- IRS: Indoor Residual Spraying
- Non-Health: Non-health products
- ANTM: Antimalarials
- ARV: Antiretrovirals
- EM: Essential Medicines
- Cond&Lub: Condoms & Lubricants
- C19RM: C19RM-related products
- Diag&Lab: Diagnostics, Laboratory consumables & other equipment
- RDT: Rapid Diagnostic Tests

¹ Note that this is exclusive of most TB volumes (i.e., all TB medicines and most TB diagnostics), which are procured through the Stop TB Partnership's Global Drug Facility (GDF).

² Volumes represent Purchase Orders placed through PPM/wambo.org; some variations in numbers between years can be a factor of the specific timing of order placement around the end of the calendar year.

³ Multi-month dispensing pack sizes are converted to monthly equivalent packs to illustrate the number of people reached for a 12-month period.

⁴ Excludes volumes procured through the ACT co-payment mechanism;

⁵ The depiction and use of boundaries are not guaranteed to be error free, nor do they necessarily imply endorsement or acceptance by the Global Fund.

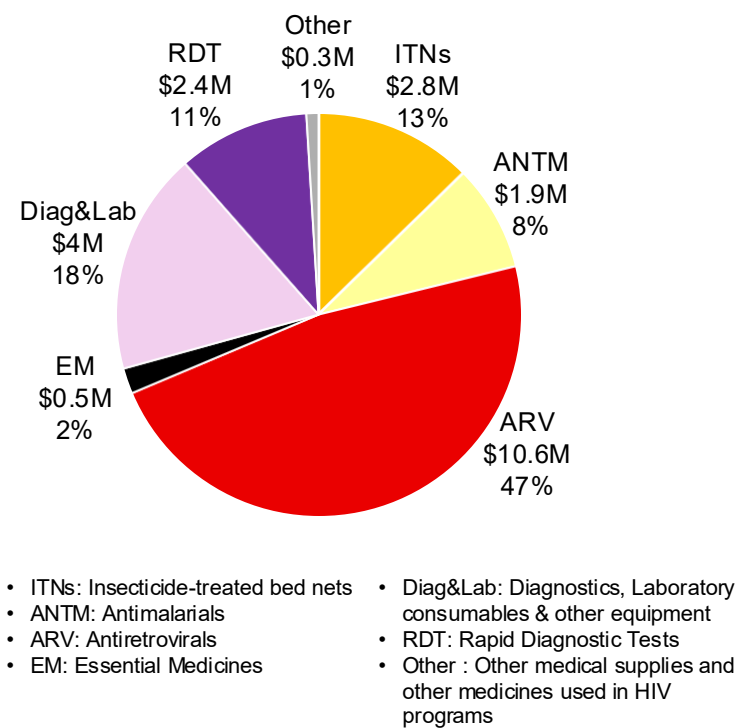
⁶ National and partner funds;

⁷ Product and procurement and supply management costs to country. Value not inclusive of revisions on purchase orders issued in prior years.

B1

In 2024 countries continued to leverage non-grant funded procurement modality through PPM/wambo.org

6 countries procured USD 22.5 M worth of health products using domestic funds, including towards their co-financing commitments¹



¹ Product and procurement and supply management costs to country.
Value not inclusive of revisions on purchase orders issued in prior years.
PPM = Pooled Procurement Mechanism

Use cases of PPM supporting non-grant funded procurement

Domestic health expenditure

Global Fund-eligible countries only, mostly using this procurement channel with domestic resources to meet co-financing commitments, ensuring access to quality assured health products at low cost. Majority of the procurements has been for ARVs.

Collaborative procurement

A >10-year collaborative procurement with the Pan American Health Organization (PAHO) Strategic Fund has enabled an additional ~US\$ 250 million ARVs outside of reported PPM transactions. It is an example of how PPM long-term supplier agreements can be leveraged to access affordable and quality assured health products through partner systems, including countries not eligible for Global Fund grant funds.

The Secretariat has noted increased interest from countries in 2025 for using the non-grant channel and is actively engaging to support access through this procurement channel.

Progress in 2024 was noted through Strategic KPIs

On-shelf availability (S8)¹

% of health facilities with tracer health products available [on the day of visit] –
Target 90%

Largely on track



HIV: 89%



TB: 81%



Malaria: 85%



High availability of 1st-line drugs across HTM. Limited availability of TB diagnostics and 2nd-line drugs for TB and malaria.

Supply continuity (S9)

% of priority products with the desired # suppliers meeting QA requirements –
Target 90%

On track



High volume products:

Target met for 12/14, only artesunate inj. and dual AI nets falling short



Low volume products:

Target met for 22/22



High supply continuity across product categories and diseases.

New Product Introduction (S10)²

% of new products introduced from an agreed list of products –
Target to be defined

On track



HIV: US\$2M partnership with CIFF to introduce PrEP ring



TB: Technical assistance for digital CXR and CAD procurement and implementation.



Malaria: Scale-up of dual AI ITNs through the Revolving Facility, US\$414M orders placed³



Key innovations introduced and scaled up through partnership & innovative mechanisms

See Annex 1 for additional details

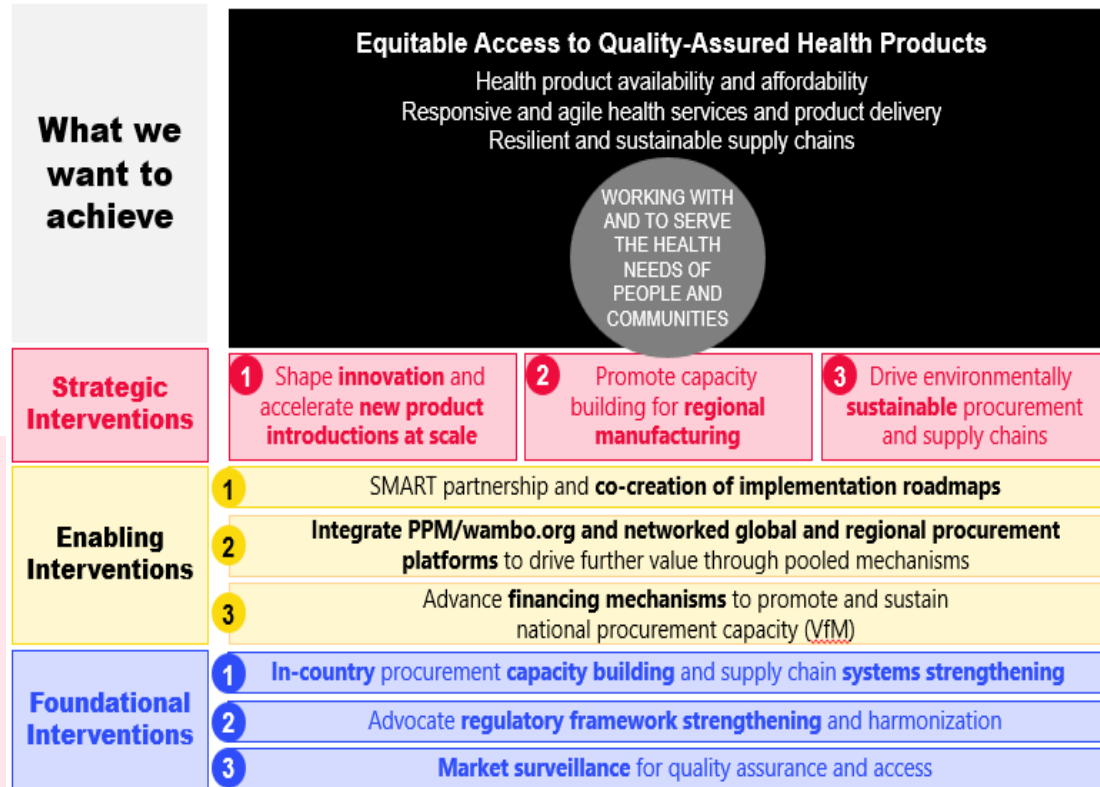
¹ OSA results already reported in Fall 2024 and based on new methodology approved by the Board in Fall 2024; no new data being reported in Spring 2025.

² No 2024 results for Key Performance Indicator (KPI) S10 on new product introductions are being reported as no target was set for 2024 in the absence of a baseline list of products agreed to be introduced that year. However, key interventions demonstrated significant successes across diseases.

³ For purchase orders confirmed in 2024, whether newly placed or issued in a prior year but revised in 2024. Includes adjustments made to 2024 POs, as of 5 Feb 2025.

AI = active ingredient; CAD = computer-assisted detection; CXR = chest x-ray; CIFF = Children's Investment Fund Foundation; HTM = HIV, tuberculosis and malaria; ITN = insecticide-treated net; OSA = on-shelf availability; QA = quality assurance; PrEP = pre-exposure prophylaxis

NextGen Market Shaping interventions have resulted in great progress, to be further leveraged to harness opportunities and address challenges ahead



Excellent progress has been made in 2024 through catalytic investments* and partnerships.

1. Rapid scale up of dual active ingredient nets
2. Continued access through PPM/wambo.org, including with domestic resources
3. First PPM delivery of African-manufactured ARVs
4. Board approval of a QA Policy for Vector Control Products and an updated Procurement Policy

To **sustain NextGen Market Shaping** progress, we need to adapt to the evolving context and challenging landscape.

This would also require continued efforts to:

1. Implement fewer priorities that have greater impact
2. Ensure choices are informed by sustainability considerations
3. Mobilize additional resources for both ongoing and upcoming interventions

Achieving cost efficiency and sustainable pricing enables scaled introduction of newer and more efficacious health products, enabling improved coverage

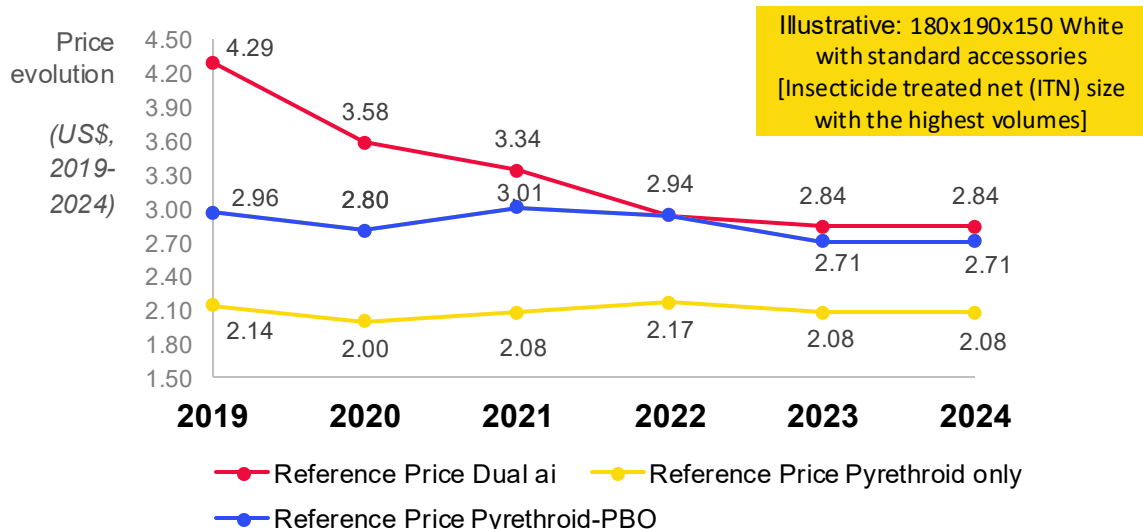
Dual active ingredient net example

Dual AI nets are expected to comprise 63% of all insecticide-treated mosquito nets in GC7.

These nets are expected to prevent millions of malaria cases with short- and long-term impact on malaria burden.

Maximizing access to effective nets

In response to insecticide resistance, introduced dual ai nets leveraging the Unitaid/Global Fund New Nets Project, the Net Transition Initiative and the Revolving Facility to advance lower and sustainable pricing from the start of Grant Cycle 7. Pricing only slightly higher than PBO nets enabled the rapid shift to more efficacious nets.

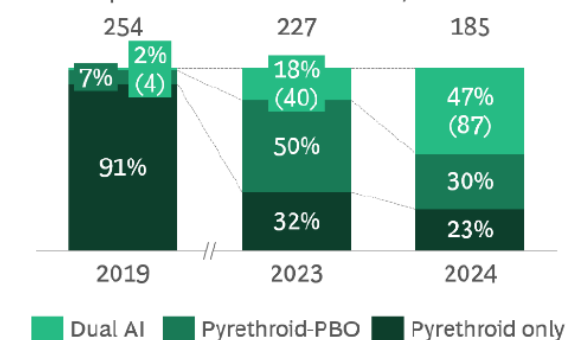


Total Dual AI unit prices 2019 - 2022 are the MedAccess-Gates-BASF volume guarantee annual prices, plus accessory costs (to ensure comparability with PBO pricing and post 2022 pricing structure).

Success was driven by:

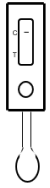
1. Effective partner mobilization and flexibility to match evolving market needs with the New Nets Project and Net Transition Initiative market entry work underpinning GC7 scale up.
2. Rapid demand mobilization, thanks to parallel efforts on evidence generation and on affordability.
3. Fast supply scale-up with innovator and next-in-class suppliers securing price at/near parity with Pyrethroid-PBO ITNs.

ITN shipments in million of ITNs, 2019A-2024A



Source: Alliance for Malaria Prevention Net Mapping Project, as of Q4 2024. Data includes Global Fund and other partner data of Global ITN shipments.

Increased the PPM procurement through Africa-based regional manufacturers in 2024



HIV Self-tests

In 2024, 200,000 HIV self-tests manufactured by a supplier based in Cape Town, South Africa were procured. This represents 5% of the 4.3M HIV blood-based self-tests procured through the Global Fund's Pooled Procurement Mechanism (PPM) to Africa.



Insecticide-treated nets (ITNs)

In 2024, more than 16.8M insecticide-treated nets were procured from an Africa-based supplier. Of nets delivered in Africa, this was 10% all ITNs and 62% of all non-dual active ingredient ITNs.



Antiretroviral and antimalarial medicines

1. First delivery of Tenofovir/Lamivudine/Dolutegravir (TLD) manufactured in Africa shipped in 2024.
2. 37% of total Artemether Lumefantrine demand to treat malaria was supplied from Africa-based suppliers. This represents a 13% increase since 2021.
3. New supplier qualified by WHO's Pre-Qualification Programme for sulfadoxine-pyrimethamine (SP) tablets for preventing malaria in pregnant women.
4. First orders for SP and amodiaquine + SP placed with an African manufacturer.
5. 61% of essential medicines procurement (in volume) for Africa was fulfilled by African manufacturers in 2024.

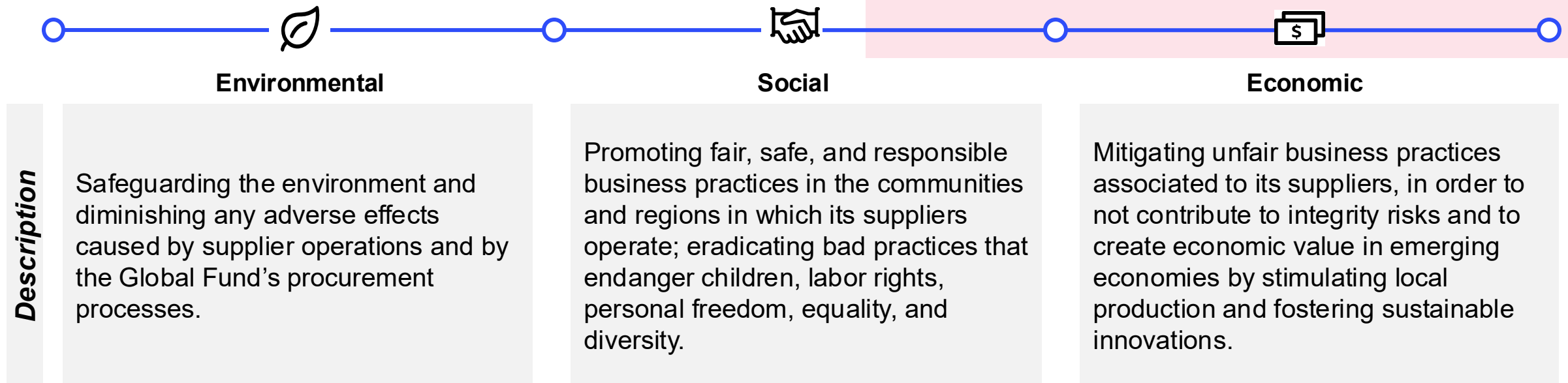
First delivery of
Africa -
manufactured
ARV TLD through
PPM in 2024



Sustainable Procurement is implemented through the Global Fund's Responsible Procurement Framework

Sustainable procurement practices are those which integrate requirements, specifications and criteria that are compatible with and favor the protection of the environment, social progress and economic development, by seeking resource efficiency, improving the quality of products and services, and ultimately optimizing costs.

The **Responsible Procurement Framework** provides the Global Fund with a clear structure and practical tools to mitigate environmental, social and economic risks related to its procurement activities. It helps buyers to implement sustainability metrics and select the right tools to reduce the procurement sustainability risks.





B NextGen Market Shaping Progress

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- 2** Ongoing NextGen Market Shaping Priorities and Outlook

To sustain NextGen Market Shaping progress, we need to adapt to the evolving context and partnership landscape

The Global Fund needs to drive continued efforts, with partners, to:

1. Implement fewer priorities that have greater impact
2. Ensure choices are informed by sustainability considerations
3. Mobilize additional resources for both ongoing and upcoming interventions

We anticipate significant challenges ahead:

1. Rapidly evolving geopolitical context
2. Changing public health landscape and funding constraints
3. Increasingly challenging partnership landscape
4. Volatilities causing market uncertainties

There are also important opportunities to be harnessed:

1. Global Fund's track record to drive efficiency and effectiveness
2. Promising health product innovation pipeline for all three diseases, across treatment, diagnosis and prevention
3. Global Fund's country model and partnerships to ensure outcomes and impact

NextGen Market Shaping provides a critical platform to accelerate access, capacity building and sustainability

Delivering on strategic priorities remains imperative for making the best tools to end the diseases available where they are needed, and to catalyze markets across geographies to enable broad access and health security

NextGen Market Shaping

Drive improved access to quality-assured health products to meet the needs of the people and communities we serve

1

Health Product Introduction & Innovation

1. Leverage market shaping tools to stabilize key markets, ensuring continued access to critical products available today at risk of market failure (e.g., pediatric HIV treatment, seasonal malaria chemoprophylaxis).
2. Incentivize innovation, prepare for introduction and accelerate scale up of better products to address the threat of drug and insecticide resistance and game-changing diagnostic, treatment and prevention tools.

2

Capacity Building for Regional Manufacturing & Procurement

- Increased importance of regional capacity for long-term market sustainability:
1. Explore use of PPM/Wambo for domestic funding, to sustain access, quality-assurance and value for money
 2. Develop pipeline of Africa based manufacturers through Global Fund's tenders and ERP mechanism
 3. Accelerate momentum on regional procurement platforms to include HTM products

3

Sustainable procurement and supply chain

1. Promote country ownership, support supply chain maturity and sustainability pathways.
2. Identify downstream supply chain efficiencies to ensure value for money while acknowledging specific country contexts.
3. Accelerate supply chain digitization and information management system integration to improve data quality and planning.
4. Explore with CRG on how to best leverage civil society and communities to support and sustain new product introduction.

Key barriers need to be addressed to accelerate progress on ongoing and upcoming opportunities [1/2]

Below are examples of key challenges and proposed mitigation actions.

Ongoing Priorities [Illustrative]



**Dual active ingredient
(dual a.i.) insecticide-
treated nets (ITNs)
scale up**

Opportunities and Challenges

Rapid and widespread progress made on this product transition in Grant Cycle 7; however, the evolving context could pose challenges in the medium / long term:

1. How do we sustain and expand the progress?
2. How to incentivize the innovation pipeline?

Proposed Way forward

1. Work with countries to maintain programmatic decisions on products, flagging clear disease control concerns around reversals of progress, embedded in appropriate prioritization.
2. Galvanize partnership efforts (Big Push and beyond) on programming and fully leveraging market shaping opportunities.
3. Mobilize additional resources through domestic and partner funding.



**Capacity building
for regional
manufacturing and
pooled procurement**

Important milestones achieved on regional manufacturing capacity building, including new product categories such as HIV professional use tests and HIV medicines (TLD). As more time and efforts will be required for additional products, we are likely to face some challenges such as:

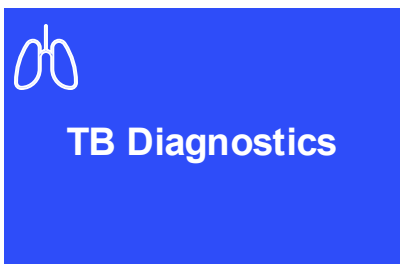
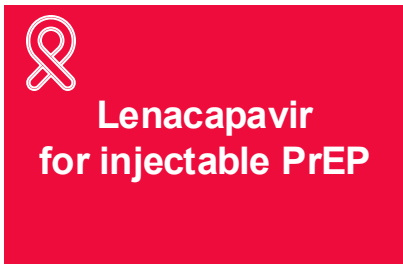
1. Trade-off between multiple market shaping priorities.
2. Economies of scale not achieved to withstand market pressures leading to low uptake.

1. Drive prioritized and complementary efforts with global, regional, and national partners.
2. Focus on selective interventions, fully leveraging Global Fund's mechanisms such as the Pooled Procurement Mechanism, Expert Review Panel, and collaborative procurement approach.
3. Continue to promote harmonized quality standards and use of reliance mechanisms to sustain progress and achieve greater efficiency and return on investments.

Key barriers need to be addressed to accelerate progress on ongoing and upcoming opportunities [2/2]

It will be important to focus on fewer, prioritized interventions and deliver them well to drive progress.

Upcoming Priorities [Illustrative]



Opportunities and Challenges

Early introduction of the new and highly effective long-acting injectable pre-exposure prophylaxis (PrEP) could accelerate the trajectory to end HIV/AIDS. Multiple challenges are faced such as an uncertain landscape, resource constraints and competing priorities to maintain essential and life-saving services. [See Annex 2 page 44.]

Malaria drug resistance countermeasure is a critical NextGen Market Shaping priority for Grant Cycle (GC) 7, to introduce additional antimalaria treatment such as Artesunate-Pyronaridine (AS-PY) and Dihydroartemisinin-Piperaquine (DHA-PPQ). A challenge ahead is our ability to sustain the diversification of antimalaria drugs with increased funding constraints. First use case of Access Fund. [See Annex 2 page 46.]

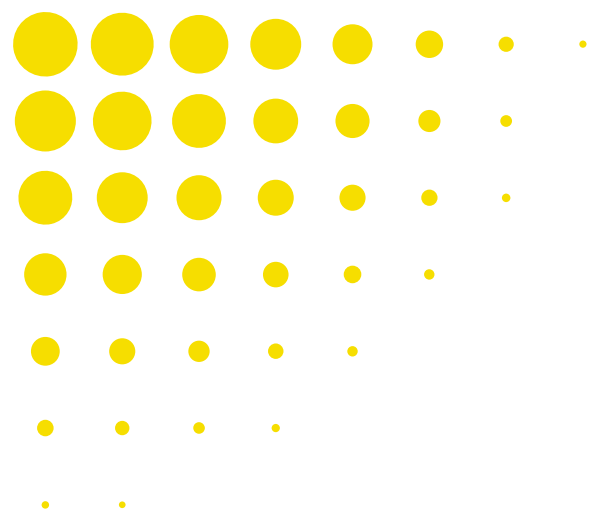
A strong pipeline of new screening, diagnosis and treatment tools for TB has been identified, including TB vaccine. However, in a constrained resourcing environment, it would be challenging to prioritize interventions for promising innovative products that would only be ready in 3-5+ years, which could further delay the development timelines. [See Annex 2 page 48.]

Proposed way forward

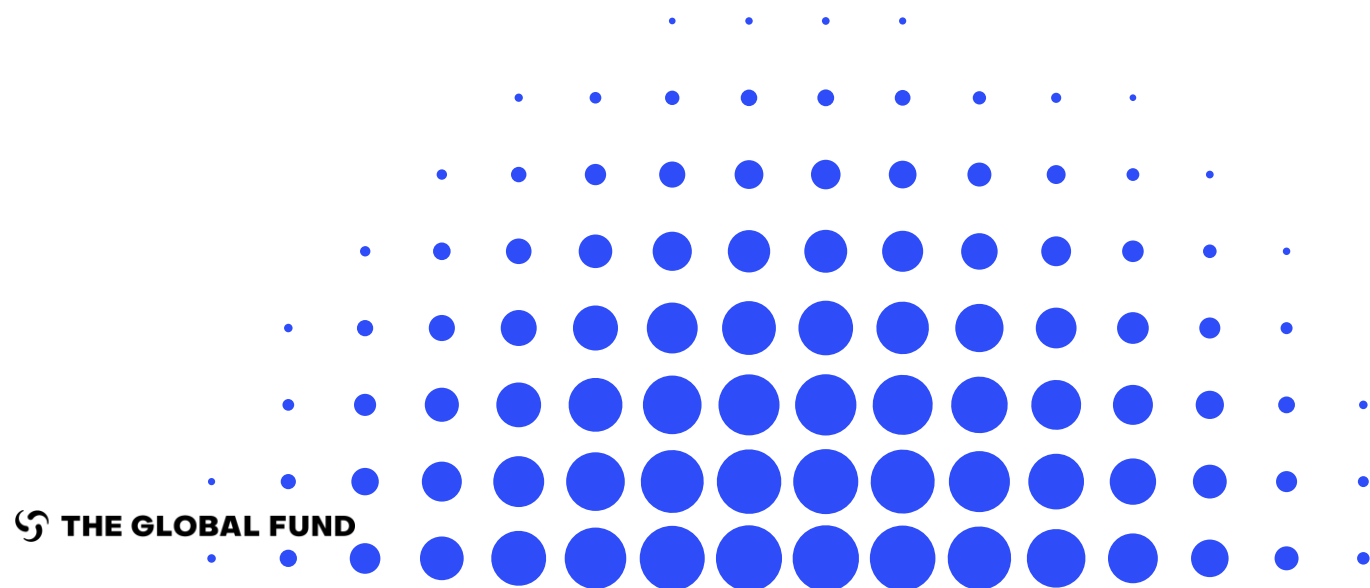
1. Accelerate affordable access and secure sustainable pricing for LEN PrEP in a phased approach [from originator to generics products].
2. Galvanize partnership efforts to realize the ambition to roll out LEN PrEP.
3. Early engagement with countries to identify areas for support to adopt and implement the new tool.

1. Catalyze demand for novel antimalarials and support country implementation across partners, leverage Big Push.
2. Drive changes to national and regional planning to ensure longevity of current suite of tools.
3. Fully leverage NextGen Market Shaping Access Fund mechanism in GC7 and prepare for program integration for GC8.

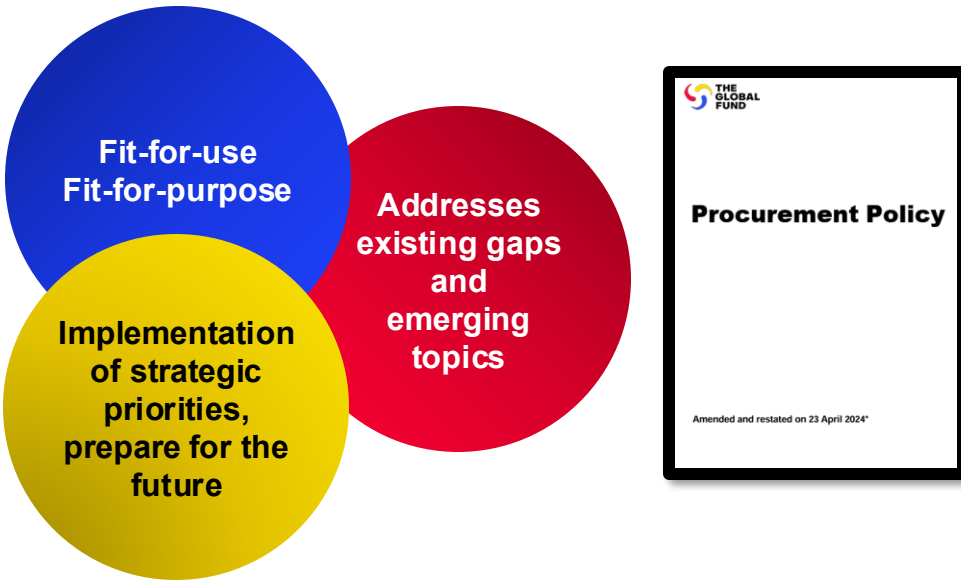
1. Work with TB partners to identify fewer and most promising innovative product solutions.
2. Continue to drive efficiency and scaling up of the existing molecular diagnostics for TB, and leverage multiplex diagnostics platform.



C Procurement and Quality Assurance Policy Implementation



New Procurement Policy and its implementation is timely to enable an improved response to the evolving context



Procurement Principles

1. Value for Money
2. Effective Competition
3. Fairness, Impartiality, and Integrity
4. Client centricity
5. Sustainable Procurement
6. Best interest of the Global Fund

Key provisions in the updated Policy

Associated benefits to respond to the current context

Collaborative Procurement

Provision to enable:

1. Ability of others to leverage Global Fund's long-term agreements, e.g., PPM / wambo.org transactions funded by domestic resources
2. Ability for partners to leverage the outcomes of procurement activities and vice versa, helps to create additional scaled synergies, efficiency and productivity gains

Sustainable Procurement

Enables a stronger focus on sustainable supply to improve resource efficiency, supply security and ultimately optimizing costs

Procurement Authority

Clearly delegated authority to the Executive Director to undertake strategic and risk-informed decisions to respond to the evolving context

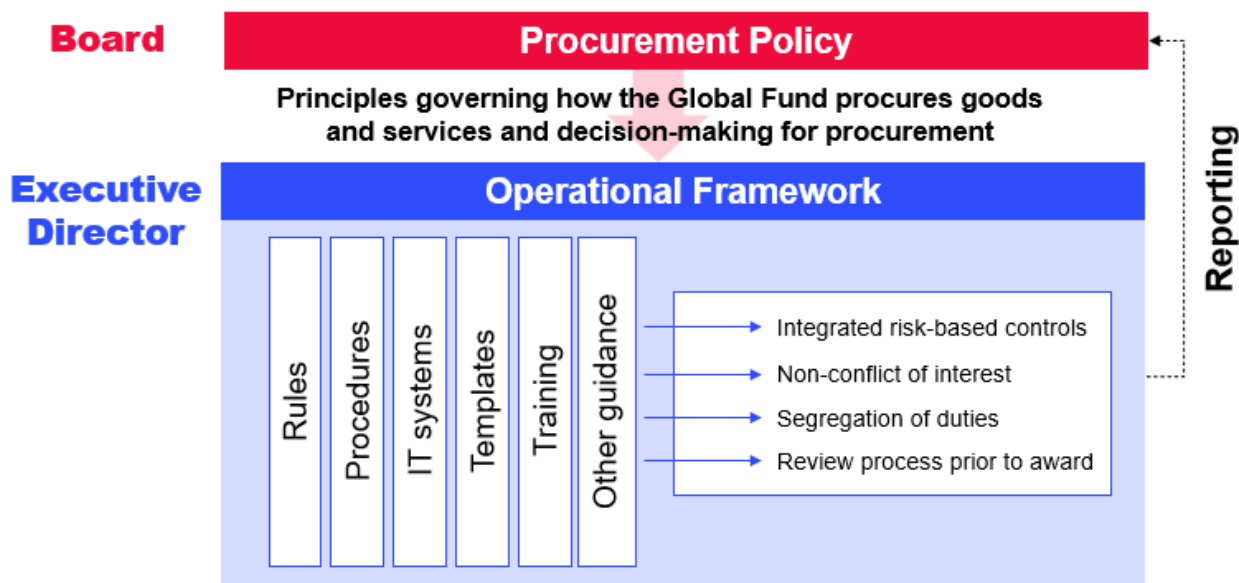
Enhanced oversight and control

Improved compliance monitoring which is critical to assurance during periods of urgency and high risk

The updated Procurement Policy is being implemented through a comprehensive operational framework

The operational framework has been designed to ensure the right balance between efficiency, effectiveness and value for money, in line with the Policy

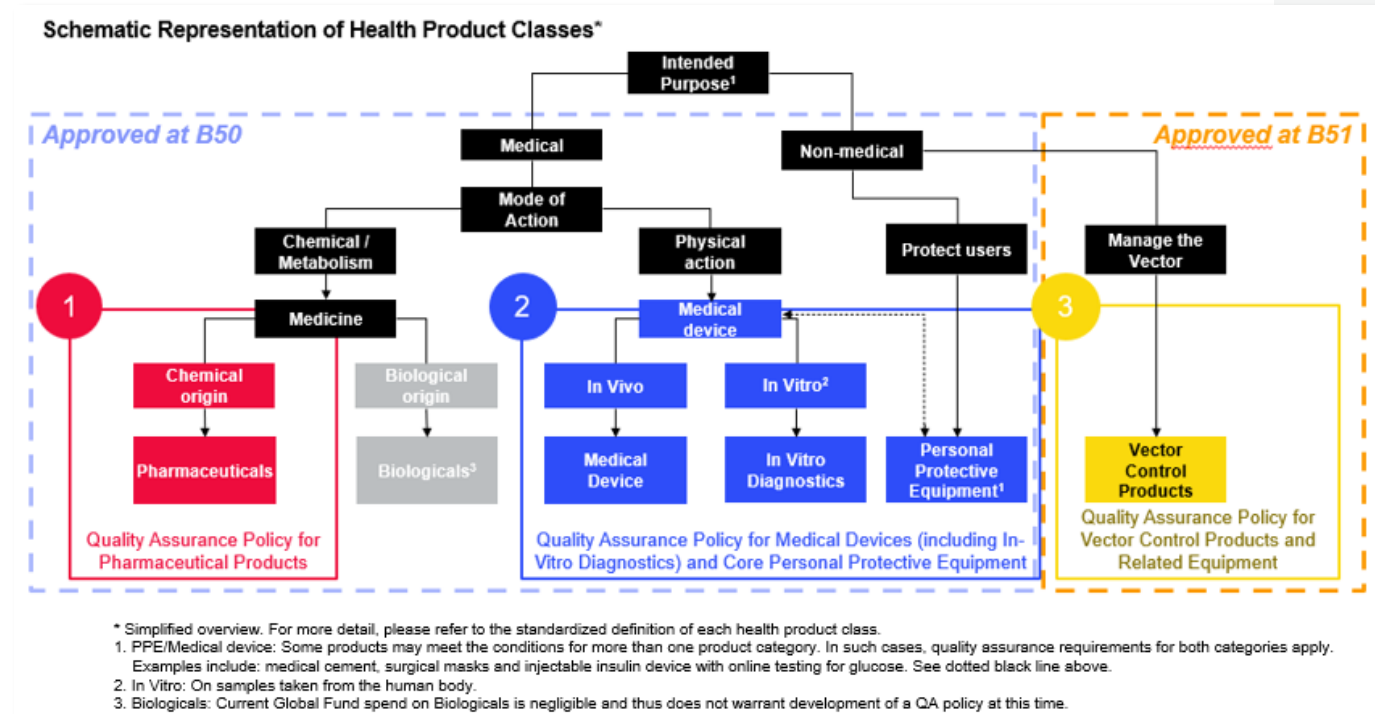
Procurement Policy Architecture



1. The operational framework has been developed with cross-functional input and includes revisions for strengthening due diligence, segregation of duties, and compliance processes. The operational framework was finalized and approved by the ED for implementation in Q2 2025.
2. Templates and capacity building materials continue to be developed alongside a change management plan. Delivery of trainings and workshops continue to progress.
3. The Secretariat intends to conduct periodical reviews to adapt and adjust the operational framework based on lessons learned.
4. Progress continues to be made on key elements introduced in the updated Procurement Policy, including Sustainable Procurement and Collaborative Procurement.

Quality Assurance Policy implementation is also ongoing and timely for responding to the current context

Board approval of the updated QA Policies in late 2023 and early 2024 was timely for clarity and for covering all product categories



Reliance

Progress on implementation of the policies helps strengthen our position for responding to the current context, through additional regulatory approval channels (i.e., WLAs).

Capacity building efforts

Countries continue to need support to realize full impact, including post-market surveillance activities.

Quality risk exposure

Pressures from constrained resources may contribute to increased risks for quality problems, e.g., when suppliers cut their own quality assurance activities as cost-saving measures, or countries procure products not approved by a stringent regulatory mechanism.

PURPOSE

1. People safety
2. Reliance mechanism
3. Harmonized QA standards

FEATURES

1. Integrated
2. Fit-for-purpose
3. Fit-for-use

APPROACH

1. Step-wise
2. Continued engagement with partners on further steps

Efforts to address implementation challenges noted at the time of approval of the QA policies are underway

Concerns had been expressed regarding country capacity to implement post-market activities and insecticide-resistance monitoring.

Key progress

1

A recent survey on selected Principal Recipients (PRs) concluded that most of the respondents did receive funds for quality monitoring of health products in their grants.

2

Of the 85 malaria endemic countries, 75 now have formal Insecticide-resistance monitoring plans.

3

Strong progress on partnership alignment around Resistance to Damage (RD) scores to support improved ITN durability and inform value for money procurement decisions, with potential guidance to be published in 2025.

Challenges and Opportunities

1

Inconsistent approaches to the execution of necessary market surveillance activities by PR. The Global Fund is developing a briefing note to provide operational guidance for product quality monitoring by PR.

2

Of the 10 malaria endemic countries without formal insecticide-resistance monitoring plans, several are in progress although continued partner support for finalizing the plans is unclear.

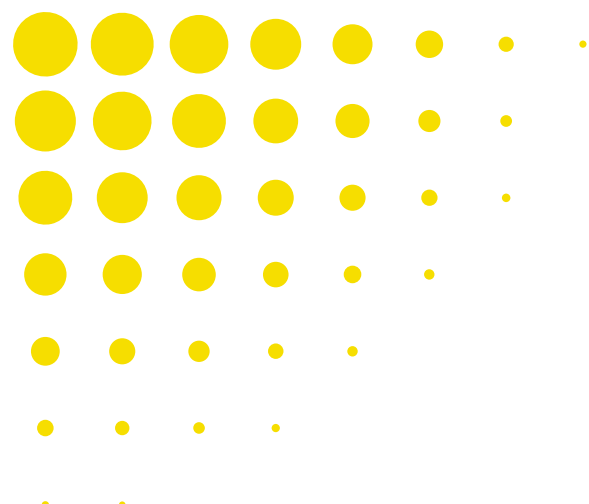
3

Ongoing lack of coherence on appropriate approach to durability monitoring for ITNs; in the meantime, performance monitoring activities continue.

Next steps

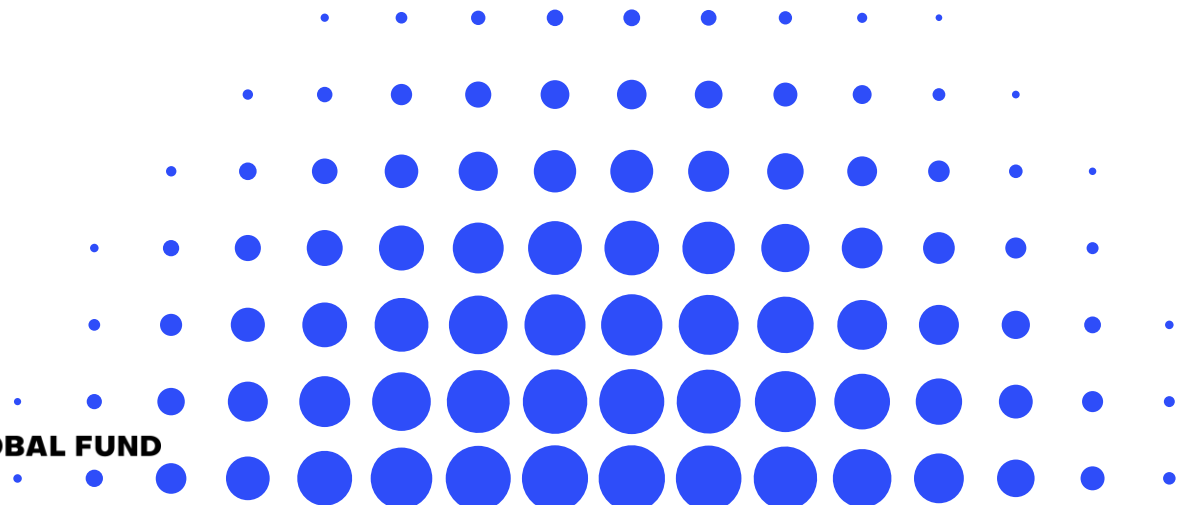
The Secretariat will:

1. Continue to drive increased efficiency and effectiveness of its procurement activities supported by the updated Procurement Policy and its operational framework, ensuring effective monitoring and integrated reporting mechanisms, including through assurance functions.
2. Leverage NextGen Market Shaping efforts to address ongoing challenges by continuing to:
 - a. Enable domestic financing of health products through the non-grant channel
 - b. Drive the stability and sustainability of key health product markets
 - c. Support regional capacity building for procurement and manufacturing for improved supply security
 - d. Build on momentum and commitment to access with partners to sustain innovation, introduction and scaling up of prioritized health product innovations



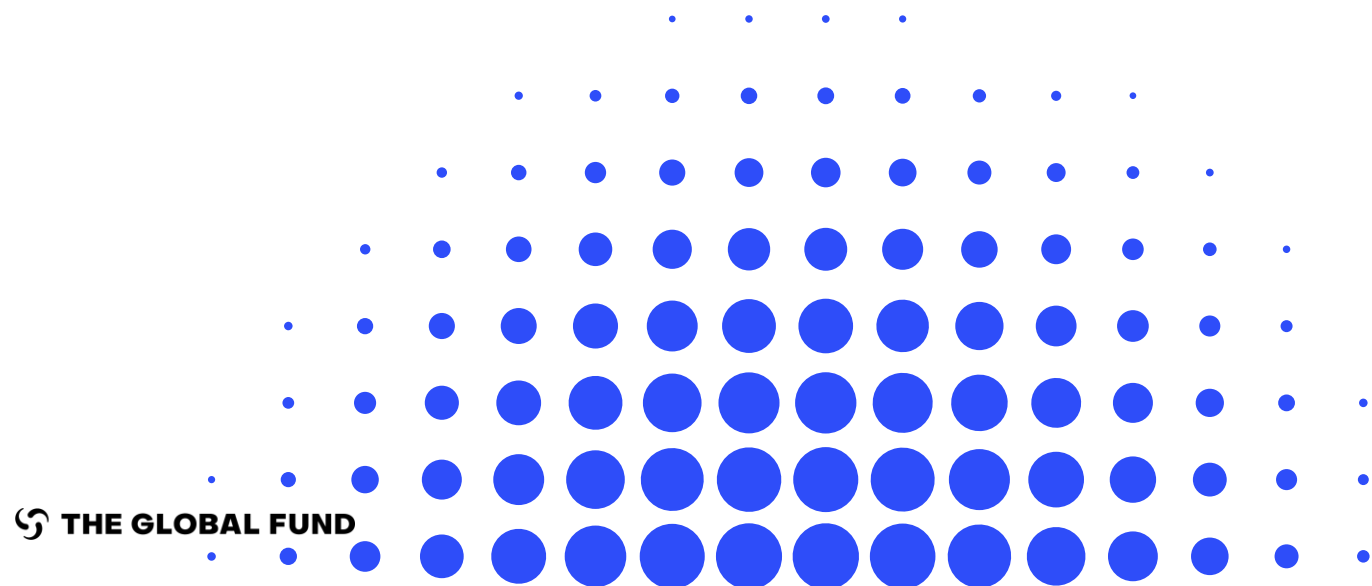
Annexes & Background Materials

- Annex 1: Additional information on KPIs S8, S9 and S10
- Annex 2: Additional information on NextGen Market Shaping work, including Strategic Initiatives
- Annex 3: Relevant Past Board Decisions
- Annex 4: Links to Relevant Past Documents & Reference Materials



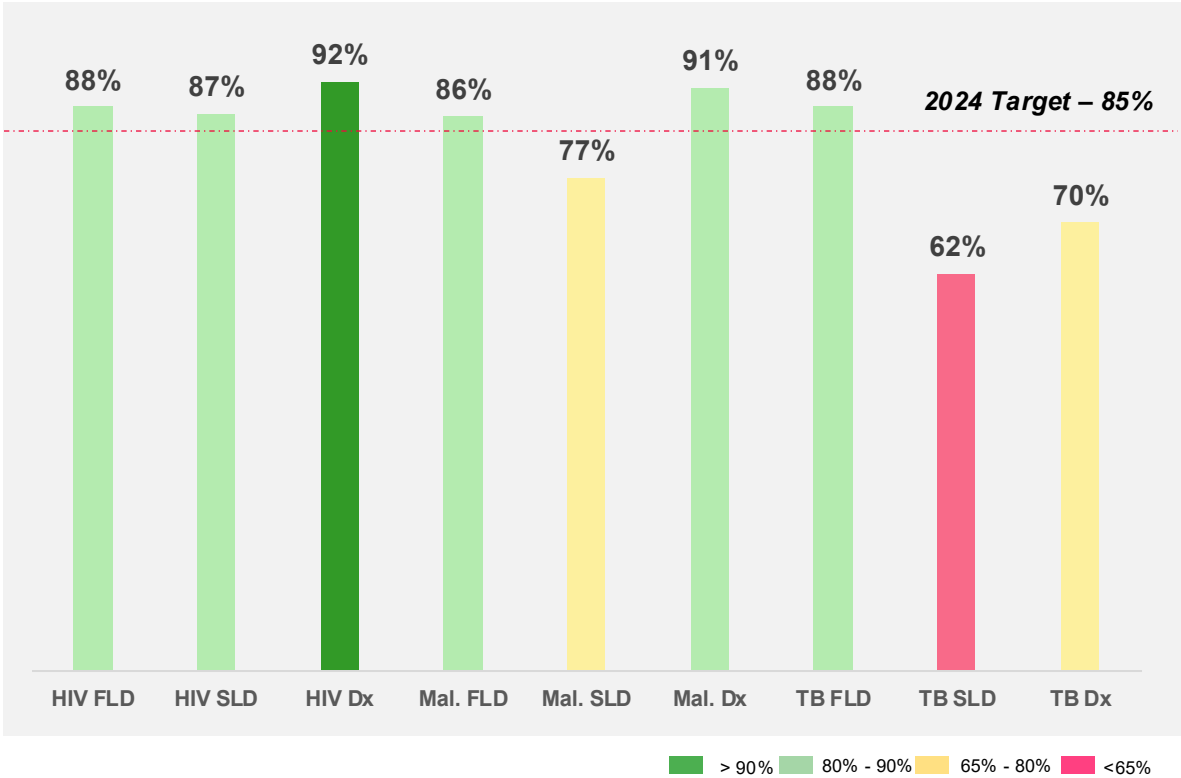


Annex 1: Additional information on KPIs S8, S9 and S10



KPI S8: On-shelf availability on promising path to achieve 2025 target of 90%

OSA scores by product category¹



Facts & Observations

KPI Performance: Largely on track

- 1. High availability of 1st-line drugs across HTM; limited availability of TB Dx and 2nd-line drugs for TB & malaria
- 2. Key drivers of product non-availability are challenges in in-country distribution leading to late deliveries, inventory management at various levels (resulting in sub-optimal storage and poor order fill rates to health facilities)
- 3. Ongoing supply chain strengthening investments (funded through GC7 & C19RM totalling US\$513 Million) aims to improve and mitigate the risks posed by the challenges and ensure consistent levels of product availability at health facilities and reach target of 90%

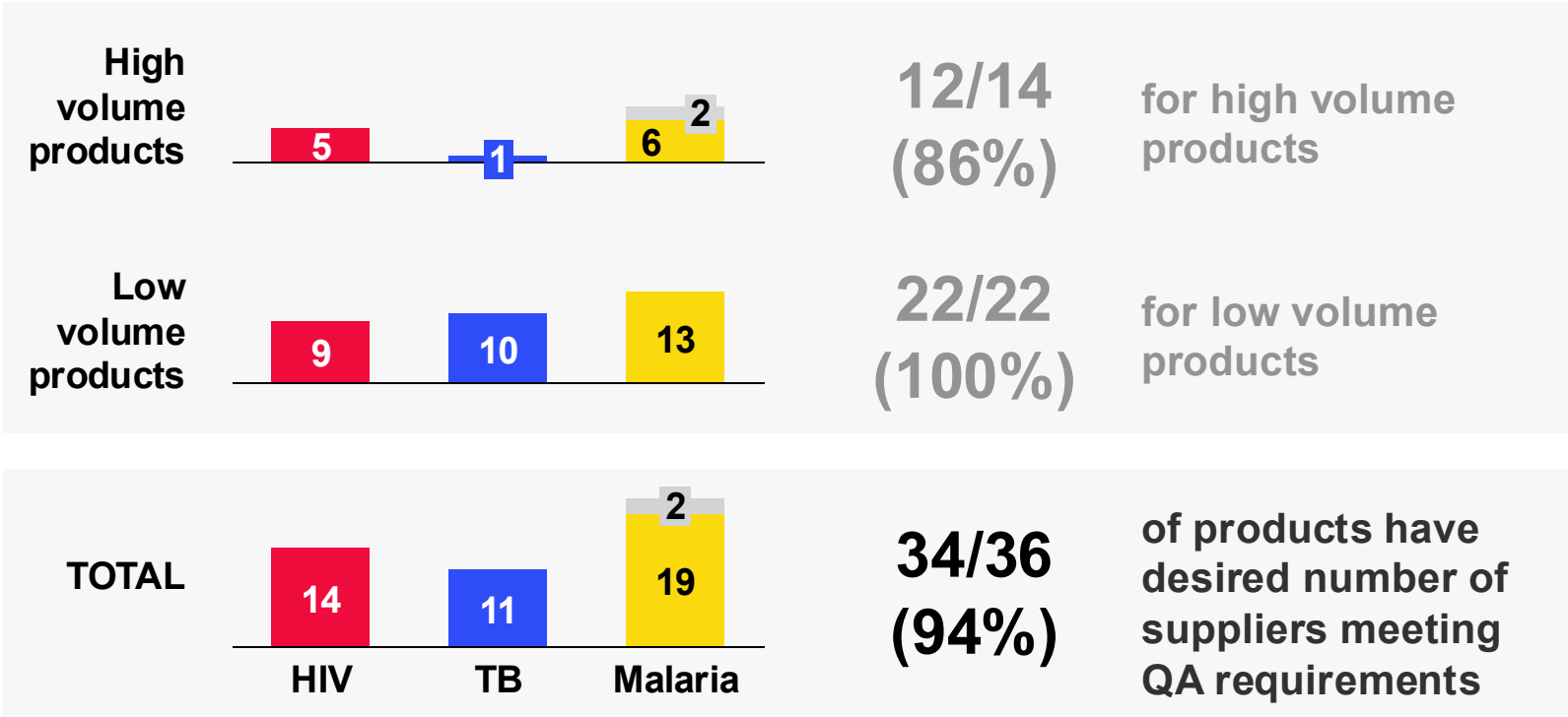
1. Data source for reporting is round 4 of spot-checks executed in 2024. Countries included are: Bangladesh, Burundi, Lesotho, Pakistan, Philippines, Senegal, Zimbabwe, Côte D'Ivoire, Togo, Guinea, Angola, DRC, Liberia, Malawi, Nigeria, Tanzania, Uganda, India, Zambia, Ghana, Madagascar, Mozambique, Burkina Faso, Cameroon, Niger, Indonesia,

KPI S9: Supply continuity on track with 94% of priority products with desired number of suppliers – Target of 90%

KPI S9 measures the percentage of priority products with the desired number of suppliers that meet Quality Assurance (QA) requirements.

Share of priority products with desired number of suppliers meeting quality assurance requirements by volume and disease

Observations



KPI Performance: On track

- Overall supply continuity & security with strong results in 2024, reflecting a stable supply base
- Minor supply constraints for certain products, *artesunate injectables 60mg* and *dual AI nets* as the only two products with fewer suppliers than desired
- Ongoing sourcing efforts and capacity building for regional manufacturing contribute to robust and sustainable supply base

Products meeting KPI target Products not meeting KPI target

KPI S10: Significant progress through scale-up of recently introduced products

Key achievements in 2024



US\$2m for PrEP Ring partnership

Early Market Access Vehicle [EMAV] launched with CIFF – first country procurement request for 24k rings worth US\$282k received in 2024

1m packs of pediatric ALD

Orders for 1m packs of pALD placed



15 countries received procurement TA

for appropriate digital CXR & CAD procurement



150m dual AI nets ordered worth US\$414m

uptake accelerated through Revolving Facility¹

Facts & Observations

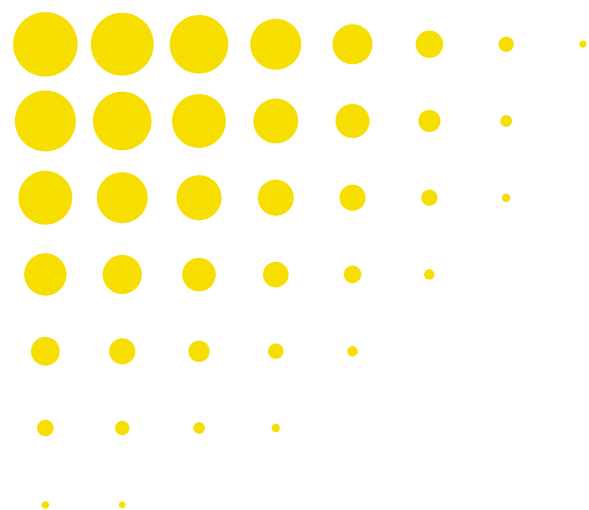
KPI Performance: No target set for 2024

- Strong progress in accelerated scale-up and uptake of new products across all diseases
- Dual AI ITN scale-up a particular success story, with 150m nets ordered by 23 countries¹
- Strong pipeline of interventions for 2025 and beyond, including the anticipated introduction of lenacapavir, ACT diversification planned through Access Fund, and the entry of a near point of care test for TB potentially using an alternative sample type.

¹ For purchase orders confirmed in 2024, whether newly placed or issued in a prior year but revised in 2024. Includes adjustments made to 2024 POs, as of 5 Feb 2025.

ACT = artemisinin combination therapy; AI = active ingredient; ALD = Abacavir/Lamivudine/Dolutegravir; CAD = computer-aided detection;

CIFF = Children's Investment Fund Foundation; CXR = Chest X-Ray; ITN = insecticide-treated net; pALD = pediatric abacavir, lamivudine, dolutegravir; TA = technical assistance



Annex 2: Additional information on NextGen Market Shaping work, including Strategic Interventions

Key activities in 2024 resulted in improved responsiveness and more sustainable procurement and supply chains

Sourcing interventions

1. Completed the diagnostics tender [rapid diagnostics tests (RDT) tender and multi-disease molecular technology] resulting in price reductions and expanded procurement modalities, including All-Inclusive pricing and anticipated clear service and maintenance terms to enhance the comprehensive diagnostics offering.
2. Updated the Procurement Service Agent (PSA) strategy to focus on enhancing supplier performance management framework. Subsequent PSA tender is a work in progress, aims to improve the overall performance of health product deliveries.
2024 progress on Reliable On-Time In-Full delivery (OTIF) shown below:¹
 - a) Manufacturer OTIF for key products (ARVs, ANTMs, ITNs, RDTs): 92% (vs. 90% target)
 - b) Procurement Service Agent OTIF: 85% (vs. 75% target)

¹ Weighted average across manufacturers or PSAs, as applicable.

ARVs = Antiretrovirals ANTMs = Antimalarial medicines ITN = insecticide treated nets

Efficient Freight/Logistics: Most shipment by sea to mitigate carbon footprint associated with freight transport.



80%
by value

95%
by volume

1. Ocean freight is preferentially utilized whenever possible and constitutes 80% of value shipped in 2024 (+1% vs. 2023).
2. Air transportation is required in some circumstances (e.g., low volumes/remote destinations not viable by sea, cold chain etc.).

Supply security: Active efforts to manage ongoing operational challenges and minimize delivery disruption to programs.

1. Enhanced monitoring given international supply chain disruption and more countries with political instability or suffering natural disasters.
2. Active monitoring of availability of raw materials to ensure stable supply and pricing.

Update on assessment of pre-financing mechanism for Pooled Procurement Mechanism (PPM) / wambo.org

As part of **sustainability considerations**, the Global Fund's Pooled Procurement Mechanism (PPM/wambo.org) can be leveraged by countries to procure affordable, quality assured health products with their domestic financing.

Several key barriers have been identified for countries to procure through the non-grant channel, including pre-payment requirements, national legislative frameworks, protection of national public procurement mechanisms and others.

Secretariat has been exploring ways to overcome some of the barriers, including the assessment of a **pre-financing mechanism**. Activities undertaken:

1. Promote PPM/wambo.org to countries that want to use it for non-grant funded transactions.
2. Leverage partner mechanisms, such as that of PAHO to gain access to PPM terms.
3. Engage with regional development banks to establish PPM/wambo.org as a preferred procurement channel.
4. Explore options for a small-scale pre-financing mechanism in wambo.org.

Based on the analysis performed and considering multiple priorities, the **Secretariat's approach** is to:

1. Continue to leverage partner mechanisms, such as that of PAHO.
2. Continue to engage with regional development banks for potential solutions to pre-financing challenges.
3. Continue to assess pre-financing options for PPM/wambo.org at the appropriate timing.

NextGen Market Shaping Strategic Initiative (SI) to drive equitable access to quality-assured health products

Global Fund 2023-2028 Vision and Strategy Implementation

NextGen Market Shaping SI

Drive equitable access to quality-assured health products to meet the needs of the people and communities we serve

1

Accelerate Health Product Introductions at scale

Revolving Facility

- Committed for Dual-AI Nets

Access Fund

- First use case: Diversification of Artemisinin Combination Therapies

Country Readiness

- Technical assistance (TA) for introduction of pediatric ALD and accelerated adoption of HIV rapid diagnostic tests
- TA to develop procurement strategies, support demand generation for country introduction of new TB diagnostics
- TA for improved quality of Therapeutic efficacy studies for antimalarial medicines
- Normative Guidance for updated guidelines

Expert Review Panel (ERP)

- Expert Review Panel for pharmaceuticals and diagnostics

2

Promote capacity-building for African manufacturing

QA Training & TA

- Quality Assurance (QA) training for African manufacturers and needs-based TA for select African manufacturers applying to WHO Pre-qualification and/or ERP

Regional regulatory networks

- TA to support establishment & maintenance of (sub-) regional regulatory networks

Regional pooled procurement

- TA to (sub-) regional pooled procurement platforms

ERP for RDTs

- ERP mechanism to accelerate access to African manufactured HIV rapid diagnostic tests (RDTs)

3

Drive in-country supply chain systems strengthening

Accelerating digitalization

- Build and strengthen capacity and capabilities for fully integrated, interoperable data systems to ensure end-to-end visibility of in-country supply chain operations

Design alternate & efficient delivery channels

- Support the implementation of people-centric, supply chains, that provide alternate channels for distribution through innovation, supply chain segmentation & ensure storage quality to increase access to and availability of high-quality health commodities at the point of service

Strategy & Governance

- Development of strong national governance mechanisms to manage the supply chains and to support development of costed national strategic supply chain planning exercises

The US\$ 49M NextGen Market Shaping Strategic Initiative has catalyzed additional funds for the Revolving Facility and the Access Fund

Key achievements have been delivered in 2024 for strategic NextGen Market Shaping Interventions

Shape innovation and accelerate new product introductions at scale

1. Secured lower access prices and increased supply capacity for the rapid introduction of CFP Dual AI nets (>45% more effective) to address biological threats to malaria, with use of the Revolving Facility.
2. Identified the first use case for the Access Fund for the diversification of artemisinin-based combination therapies (ACTs) to combat drug resistance.
3. Provided technical assistance to countries to support country readiness for accelerated health product introductions: Digital CXR and CAD for TB, Readiness assessment and demand generation for TB diagnostics.

Promote capacity building for regional manufacturing and procurement

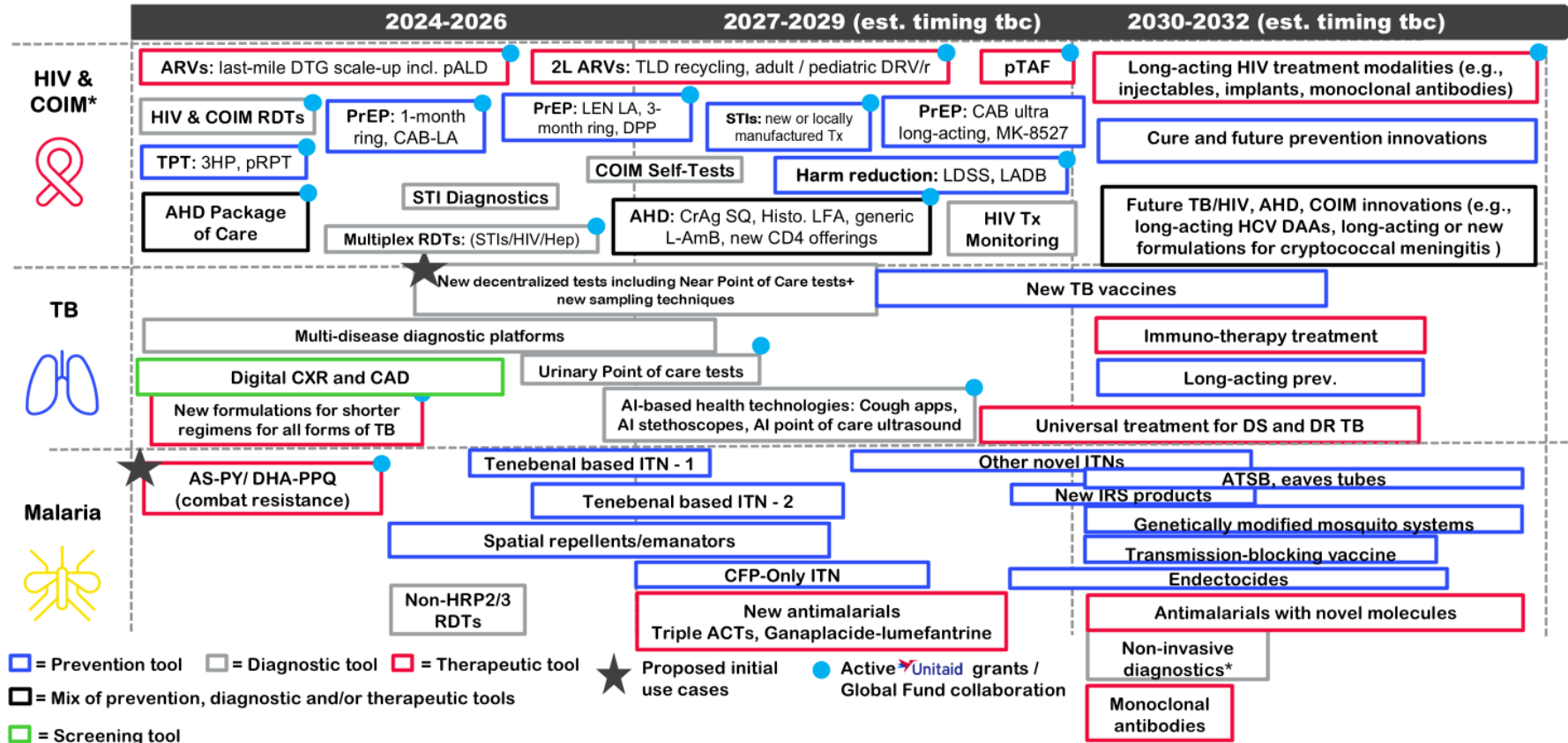
1. First supply of quality assured ARVs from Africa, in addition to continued regional procurement of insecticide-treated nets, antimalarial medicines and essential medicines.
2. Completed preparations to support rapid verification studies of HIV diagnostic tests, for updating of national testing algorithms, expanding access to regionally produced quality assured diagnostic tests.
3. Launched capacity building for regional procurement platforms within Africa and between Africa and Latin America to support sustainable procurement.

Drive environmentally sustainable procurement and supply chains

1. Supporting execution of key supply chain system investments from C19RM, GC7 and catalytic investments in 25+ countries
2. Supported in going live and uptake of two critical digitalization initiatives:
 - a. ERP roll-out in Ethiopia (EPSS)
 - b. eLMIS system in The Gambia
3. With partners, convened a supply chain leaders' forum with more than 30 countries to drive collaboration and champion critical interventions to transition to sustainable and equitable supply chains.
4. Initiated Supply Chain leadership program (STEP) for Kenya and SADC region
5. Continued PPM optimization of ocean freight in 2024 to reduce carbon emissions associated with delivery

Efficiencies, prioritization and partnerships are key to enable market shaping efforts to drive accelerated introduction of new products

Mapping as of
February 2025



1. The Global Fund and partners continue to monitor the product pipeline across grant cycles to inform and prioritize market shaping.
2. Together with partners, the Global Fund assesses which products would benefit from market shaping tools according to the barriers to introduction or scaling, market dynamics and potential impact.
3. Prioritizing products with the greatest impact helps grant investments go further.

Illustrative, not exhaustive. Reflects work with many other partners not shown here.

Future plans subject to availability of funds

*variety of biomarkers and technology platforms, including lateral flow test platforms; novel biomarkers; hemozoin detection, and volatile biomarker signatures and technologies

AHD = Advanced HIV disease

*COIM = Co-infections and co-morbidities
Dual-AI = Dual active ingredient

EVT = Elimination of vertical transmission
POC = Point of care

Innovation: HIV Health Product Introduction

Workstream	Key objectives	Planned Deliverables (GC7)
1 HIV Prevention	Accelerate HIV incidence reduction through expedited access to new and existing HIV prevention products within the choice toolkit	<ol style="list-style-type: none">1. Accelerated introduction of new PrEP products including long-acting injectable cabotegravir, the 1-month dapivirine vaginal ring (PrEP ring), and long-acting injectable lenacapavir. Improved last-mile distribution of condoms / lubricants2. Concluded preparations w/ Unitaid for the introduction of low-dead space syringes and needles and long-acting depot buprenorphine
2 HIV Treatment	Accelerated introduction and scale-up of dolutegravir-containing regimens for adults, adolescents, and children	<ol style="list-style-type: none">1. Last-mile TLD introduction and scale-up, with a focus on driving price reductions given significant demand2. Increased number of countries and children access pediatric abacavir/lamivudine/dolutegravir (pALD) (facilitated by the NextGen Market Shaping Initiative)
3 HIV Testing	Improve HIV testing while driving lower prices and stimulating manufacturing closer to product use	<ul style="list-style-type: none">• Increased access to lower-costing as well as African manufactured HIV tests (facilitated by the NextGen Market Shaping Strategic Initiative)

Key Achievements in 2024

1. First orders for new commodities:
 - a. Pediatric ALD, over 1M bottles
 - b. CAB LA, 126k vials
 - c. PrEP ring, 90k rings
2. Established PrEP Ring Early Market Access Vehicle (EMAV) w/ CIFF to facilitate immediate access to up to 150K PrEP rings. This was also accompanied by a 10% price reduction in the one-month ring.
3. Substantial price reduction for TLD, the first-line HIV treatment from \$71 to \$37 per person per year*

Market Shaping

Opportunities

1. Expand choice and access to more convenient, long-acting prevention tools, such as Lenacapavir.
2. Foster market competition for generic pre-exposure prophylaxis (PrEP) options for improved availability and access.

Challenges

1. Long-acting ARVs and innovative prevention tools remain expensive, limiting access in low- and middle-income countries.
2. Complexities associated to regional manufacturing.

Update on Lenacapavir for PrEP, an innovative, highly effective injectable HIV Pre-exposure prophylaxis (PrEP)

Key opportunity

Lenacapavir is a 6-month injectable HIV PrEP drug that has shown tremendous promise in recent trials with up to 100%^{1,2} success in preventing new HIV infections. If rolled out at scale and as part of a broader HIV prevention package, it has the potential to substantially bend the epidemic curve and accelerate progress towards the 2030 global HIV goals. Reducing new HIV infections would result in a reduction of HIV treatment costs over time, improving the success and sustainability of HIV programs.

Approach

1. **Coordinated secretariat-wide support** on LEN PrEP offer, identification of needs and TA requirements for introduction and scale-up
2. **Country-led determination of needs** to ensure programs, platforms, and communities are prepared for rapid introduction and scale-up of LEN PrEP
3. **Coordinated partnership-wide support** to meet needs and TA requirements
4. **Identification and utilization of funding streams** - potentially including grant funds, NGMS SI and additional contributions

Introduction for scale [Originator]

Further scale up [Voluntary Licenses]

Access and Procurement

1. Ongoing contracting with originator, supply arrangement finalization expected **end of Q2 2025**
2. National regulatory approvals for early adopter countries expected to be in place by Q4 2025

Clinical and regulatory

1. Originator has filed w/ the US FDA; approval expected **as early as June 2025**
2. Market authorization and EU-Medicines for All applications submitted to European Medicines Agency in February 2025
3. WHO recommendation anticipated **by July 2025**

Country implementation

1. Engage potential early adopters of LEN PrEP
2. Support introduction planning across countries in S2 2025 with earliest first introduction occurring in at least one country **by end 2025/Q1 2026**

1. Support accelerated generic development and product availability through direct engagement and support to voluntary licenses
2. Supply from generic manufacturers **expected in 2027**

1. Generic suppliers expected to meet regulatory requirements, ensuring bioequivalence, stability, and Good Manufacturing Practices (GMP).
2. First regulatory approval for a generic by **2027**

1. Generic entry and rapid scale-up will build on service delivery platforms and experiences of originator launch
2. Implementation planning to **begin from 2026**

Innovation: Malaria Health Product Introductions

Workstream	Key objectives	Planned Deliverables (GC7)	Key Achievements in 2024
1 Access Fund	Utilize a co-financing mechanism to enhance the affordability, adoption, and demand for Artesunate-Pyronaridine (AS-PY) and Dihydroartemisinin-Piperaquine (DHA-PPQ) to delay drug resistance by diversifying the artemisinin combination therapy (ACT) portfolio through proactive therapeutic deployment approaches like multiple first line therapies (MFT).	<ol style="list-style-type: none">1. Increased adoption of MFT strategies to delay emergence/spread of artemisinin and/or partner drug resistance2. Increased affordability of AS-PY and DHA-PPQ by reducing the price differential to Artemether-Lumefantrine (AL)	<ol style="list-style-type: none">1. Secured lower access prices and increased supply capacity for the rapid introduction of Chlorfenapyr Dual AI nets (>45% more effective) to address biological threats to malaria. Dual AI nets are expected to comprise 63% of all insecticide-treated mosquito nets in Grant Cycle (GC) 7.
2 Revolving Facility	Accelerate health product introductions at scale	Advanced market commitment to secure affordable pricing for dual active ingredient (dual AI) insecticide-treated mosquito nets	<ol style="list-style-type: none">2. Expanding ACT options in priority countries to reduce overreliance on AL.
3 Regional Initiatives	Strengthen antimalaria drug efficacy and resistance surveillance in Africa	Improving GF funded Therapeutic Efficacy Studies adherence to WHO protocols, ensuring quality, and enhancing in-country capacity	<ol style="list-style-type: none">3. Established a partner group to coordinate support for countries in addressing antimalarial drug resistance and making informed policy and programmatic decisions.

Market Shaping

Opportunities

1. Facilitate development and market entry of next-generation insecticides and bed nets by incentivizing research and development through advanced market commitments or subsidies.
2. Increase adoption of MFT strategies to diversify treatment options and delay resistance by addressing pricing and procurement challenges.

Challenges

1. The emergence of resistance threatens the efficacy of current tools, requiring costly innovation and market diversification.

Update on driving accelerated uptake of diversified anti-malarial medicines to address resistance: First Use Case for Access Fund

Access Fund will catalyze and amplify Global Fund’s market shaping efforts supporting ACT diversification, delivering early success to build a case for increased diversification of 1st line malaria therapies

CATALYTIC FUNDING FOR THE ACCESS FUND

Global Fund has allocated \$14M from the NextGen Strategic Initiative (SI) to establish an Access Fund. Gates Foundation investment of \$5M received to support additional countries to introduce new products and further demonstrate proof-of-concept as an effective tool

WHAT IS THE ACCESS FUND?

- 1. A centrally-managed fund providing temporary co-payments for product procurement using country grants.
- 2. Part of the Global Fund’s market shaping toolkit, alongside the Revolving Facility, country readiness support, and regulatory assistance.
- 3. Helps seed demand, scale economies, and bridge market evolution until prices drop or willingness to pay increases.

HOW WILL IT WORK?

Principles for product selection:

- 1. **Urgency:** Addresses an urgent need or emerging threat.
- 2. **Catalytic:** Enables uptake that would not happen otherwise.
- 3. **Sustainable:** Paves the way for long-term adoption at scale.
- 4. **Market-shaping:** Enhances broader market-shaping efforts.

Design:

- 1. Co-pay amount determined by product, covering up to the difference between legacy- and new product.
- 2. Available to a subset of countries based on need, demand and introduction readiness
- 3. Duration determined by expected evolution in supply- and demand-side market dynamics.

FIRST USE CASE



- 1. Malaria remains a leading cause of child mortality, with over 1,000 children under five dying daily, mostly in Africa.
- 2. While 6 WHO-recommended ACTs exist, over 80% of ACTs procured in sub-Saharan Africa are AL. **ACT diversification** following a WHO recommended strategy is a way to slow down or prevent the emergence of drug resistance.
- 3. With confirmed drug resistance in four African countries—likely underestimated due to surveillance gaps—there is an urgent need to diversify 1st line treatments.
- 4. The Access Fund aims to help countries adopt alternative, more expensive treatments like AS-PY and DP, at no extra cost to the grants, thereby strengthening the response to drug resistance while mobilizing demand to drive economies of scale and lower prices.
- 5. This effort aligns with the Malaria Big Push agenda, providing targeted financial support to scale up effective interventions and accelerate progress toward malaria elimination by 2030.

Status

- 1. In collaboration with partners, Burkina Faso, Ghana, Malawi and Uganda have confirmed to be the first countries.
- 2. Quantities and delivery timelines agreed for procurement to be transacted in 2025.
- 3. Ongoing engagement with wider partner ecosystem through bi-monthly Global Partners Call on ACT diversification to ensure alignment and efficiencies.

Innovation: Tuberculosis Health Product Introduction

Workstream	Key objectives	Planned Deliverables (GC7)	Key Achievements in 2024 1. Successfully conducted a global tender process for multiplex diagnostic platforms. 2. Convened a regional workshop in Cote d'Ivoire with over 35 African countries to support demand generation and implementation planning for new TB diagnostic and screening tools. This will ensure quicker adoption of new diagnostics once available. 3. Providing technical assistance to 15 countries to ensure appropriate procurement of Digital Chest X-ray (CXR) and computer-aided detection (CAD) including supporting national procurement discussions. Resulting in procurement savings of over US\$1M in Ethiopia.
1 TB screening and diagnostics	Improve access to new quality TB screening and diagnostic tools.	1. Define market size for new diagnostics 2. Convene regional meetings to support country readiness including demand generation and implementation planning 3. Technical assistance for deployment of Chest X-ray and computer-assisted diagnosis and new additional molecular diagnostics that might get WHO recommendation in Grant Cycle (GC) 7.	
2 Reduced pricing of health products	With partners, support lower sustainable pricing contributing to more equitable access to affordable quality assured health products	Reduced pricing for TB screening, treatment, diagnostics as well as improved care for equipment service and maintenance.	

Market Shaping

Opportunities

- 1. Adoption of shorter treatment regimens (e.g., BPaL, 4HPMZ) for drug-resistant TB by addressing barriers such as affordability, registration, and healthcare worker training.
- 2. Expand access to rapid molecular diagnostic tools through pooled procurement and partnerships to lower costs and increase availability of new platforms in the pipeline.

Challenges

- 1. The high cost of diagnostic tools poses significant affordability challenges to achieving the UN High Level Meeting target of 100% access to molecular diagnosis, with limited global funding available to subsidize them.

Utilizing the NextGen SI to support improved country readiness and early access to new, quality TB screening & diagnostics

Key opportunity:
Expanding the TB diagnostic market is key to breaking the current monopoly and accelerating access to innovative tools. New near Point of Care platforms and alternative sample types coupled with multi-disease platforms will improve decentralization and case finding. The introduction of tongue swab sampling and a near point of care test —requires strategic planning and investment to ensure successful implementation building on previous diagnostic investment..

Approach:

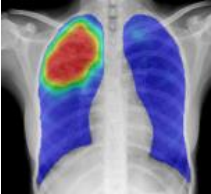
1. Provide demand-driven technical assistance to countries to develop procurement plans, support demand generation activities in preparation for the introduction of new TB screening and diagnostic tools
2. Promote regional knowledge sharing to drive demand generation and support effective implementation planning for new TB diagnostics. This will enable countries to learn from each other’s experiences, streamline adoption, and accelerate scale-up.

NextGen SI Support		
	Component	Activities
1	Market size estimation to support and enable at-scale introduction of new TB Diagnostic tools	<ul style="list-style-type: none">• Support baseline assessment of WHO Diagnostic standards• Use existing DNO/DNAs to identify potential procurement needs for new low complexity NAATs, near POC platforms• Landscaping/mapping of CXRs & CAD in country
2	Regional engagement to support demand for introduction of new diagnostic tools	<ul style="list-style-type: none">• Facilitate regional platforms for knowledge sharing to support potential demand generation and implementation planning
3	Technical assistance to translate normative guidance into national strategies and planning	<ul style="list-style-type: none">• Provide technical support for guideline updates, trainings, etc. for new diagnostic tools.

Priority Products


CXRs with CAD/AI software

- Opportunity for more sensitive screening for TB including retrofitting existing hardware with CAD/AI software.
- Multiple new software providers entering the market
- Opportunity to standardize CAD procurement practices




New sampling techniques with near Point of Care tests

- Tongue swabs or swabs in sputum samples
- Potentially very large market, depending on the indication
- Use in new near point of care platforms
- GDG Q4 2025 may give guidance



Low complexity diagnostics

- Multi-disease platforms
- Similar space as GeneXpert and TrueNat
- Additional competition to market with potential lower prices and better S&M
- GDG Q2 2024 gave a class-based recommendations. One product submitted for ERP, others in the process.

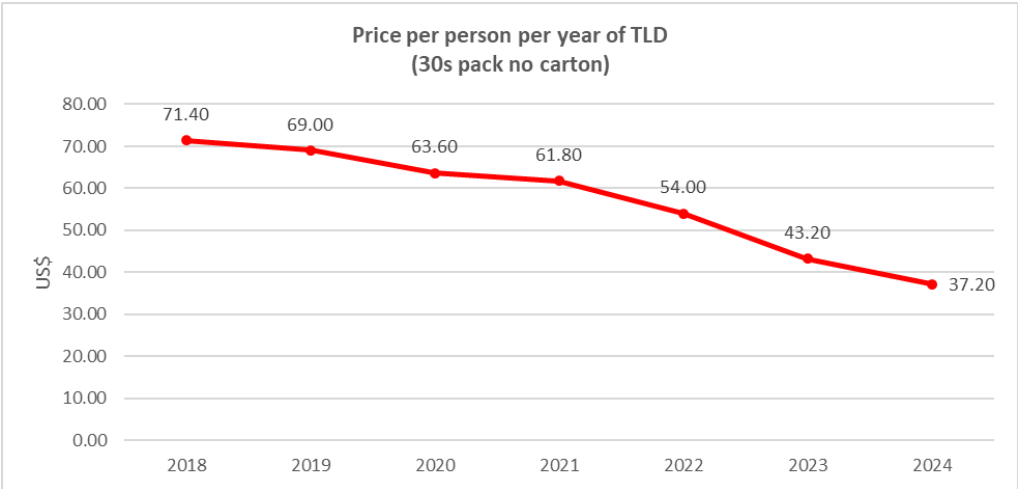


Achieving cost efficiency and sustainable pricing enables scaled introduction of newer and more efficacious health products, enabling improved coverage

Illustrative examples

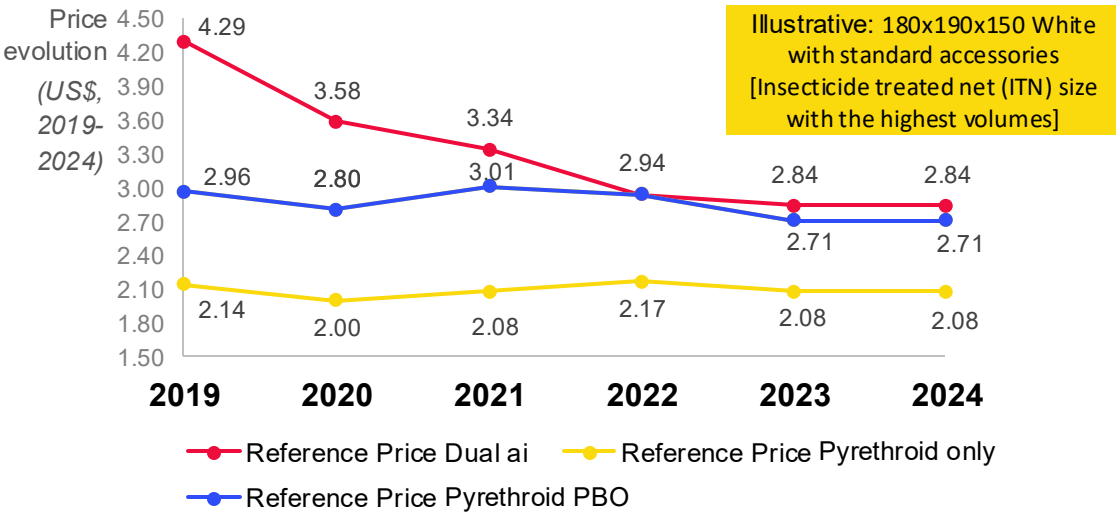
Anti-retroviral medicine

From TLD introduction in 2018, Global Fund and partners have worked with manufacturers to achieve sustainable pricing of below US\$ 40 per person per year, a 48% reduction over six years.* These cost savings have allowed expanded coverage and generated more economies to increase the HIV portfolio, including HIV prevention and new pediatric product introductions.



Dual active ingredient net

Building on joint partnership efforts, we have collectively shaped the ITN market to maximize access to effective nets. In response to insecticide resistance, the Global Fund has introduced dual ai nets leveraging the Unitaid/Global Fund partnership New Nets Project, the Net Transition Initiative and the Revolving Facility to advance lower and sustainable pricing right from the start of Grant Cycle 7.

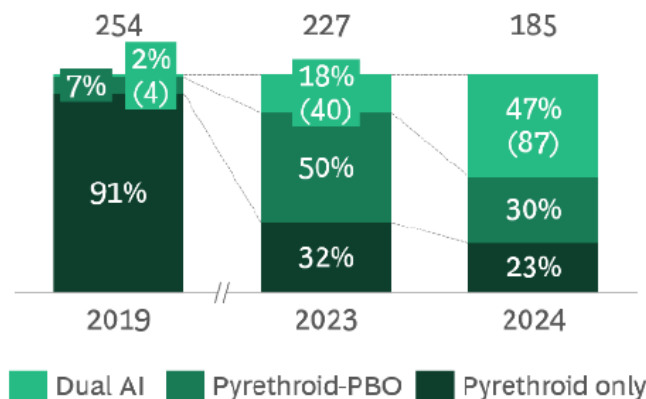


Update on rapid scale up for dual active ingredient nets – countermeasure against insecticide resistance

Collective response

1. Building on a multi-year, effective partnership effort, the Global Fund has supported the rapid transition to more efficacious insecticide-treated nets (ITNs) in Grant Cycle (GC) 7.
2. By combining two different classes of insecticides, these nets ensure that mosquitos resistant to one type are still killed by the second.
3. With our Revolving Facility and negotiation power, we were able to secure prices for dual active ingredient (AI) nets only slightly higher than the prices of piperonyl butoxide (PBO) nets, enabling countries to more rapidly make the shift to more efficacious nets.

ITN shipments in million of ITNs, 2019A-2024A



Source:
Alliance for Malaria
Prevention Net Mapping
Project, as of Q4 2024.
Data includes Global
Fund and other partner
data of Global ITN
shipments.

Key enablers

Success was driven by:

1. Effective partner mobilization and flexibility to match evolving market needs with the New Nets Project and Net Transition Initiative market entry work underpinning GC7 scale up.
2. Rapid demand mobilization, thanks to parallel efforts on evidence generation and on affordability.
3. Fast supply scale-up with innovator and next-in-class suppliers securing price at/near parity with PBO ITNs.

Lessons learned for future

We conducted an external assessment of lessons learned from the accelerated Dual AI ITN transition for application for future product introductions.

While the joint partner efforts and scaled introduction are seen as great success, key learnings include:

1. Ensure that collective market shaping efforts address pre-market entry needs to best position for the scale-up phase.
2. Ensure alignment and balance of strategic, programmatic and market perspectives for success.

Dual AI nets are expected to comprise 63% of all insecticide-treated mosquito nets in GC7.

These nets are expected to prevent millions of malaria cases with short- and long-term impact on malaria burden.

Driving downstream efficiency is critical to improve responsiveness and maximize outcomes: Cost optimization for last mile delivery in Nigeria, saving ~US\$1.4m

1. Modelling of routes and last mile distribution costs were undertaken to enhance the **visibility of cost drivers** to enable the **management of value for money**.
2. The cost benchmarking for the respective States facilitated **the review of third-party logistics [3PL] bids and the investigation of gaps** between estimated cost and supplier prices.
3. The **cost modelling identified issues and inefficiencies**, including low truck utilization and route sub-optimization.
4. Once the efficiencies were applied, the costs of last-mile distribution went down by **31%**, because of this intervention, generating **~\$1.4m** dollars of cost-reduction to the negotiated contract 3PL sub-cost for the 2021-2023 period. Efficiency gains continue into Grant Cycle 7.

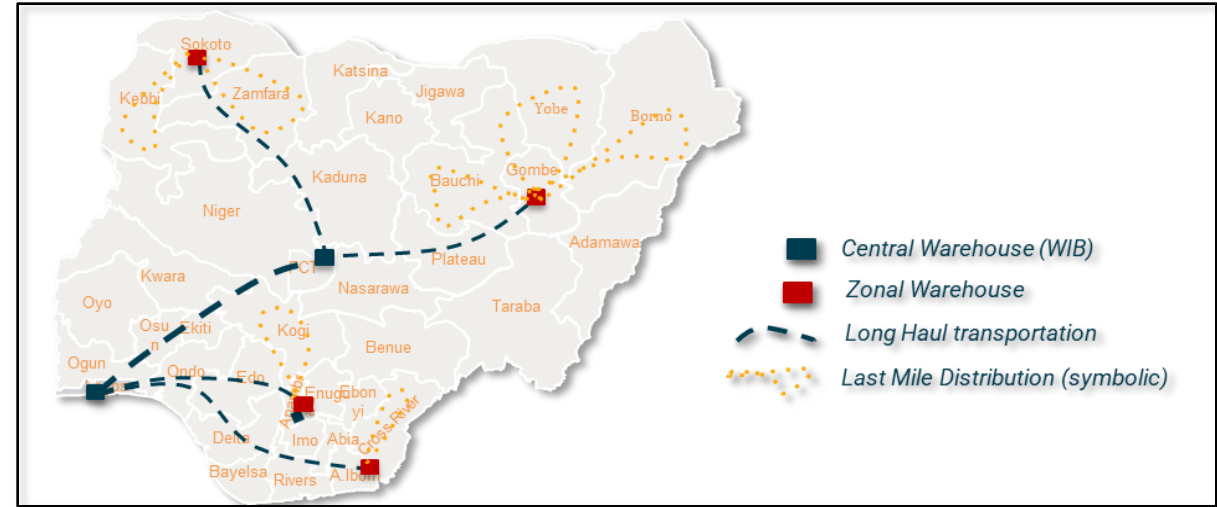


Figure depicting warehousing and distribution network in Nigeria

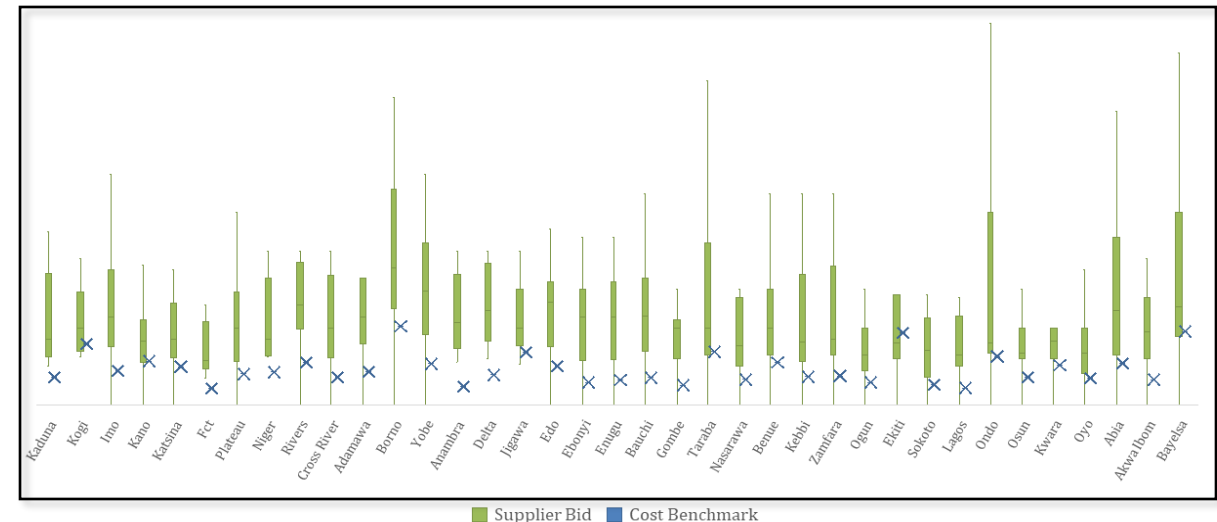


Figure presenting average initial cost of 3rd party logistics bids vs. benchmarked costs

Operational efficiency through digitalization: optimize pharmaceutical supply services enables financial self-sufficiency in Ethiopia by saving US\$1 million annually

Enhanced Performance Monitoring

Provides comprehensive insights for performance monitoring at all levels, enabling proactive cost management, product expiry tracking, lead time optimization, and more.

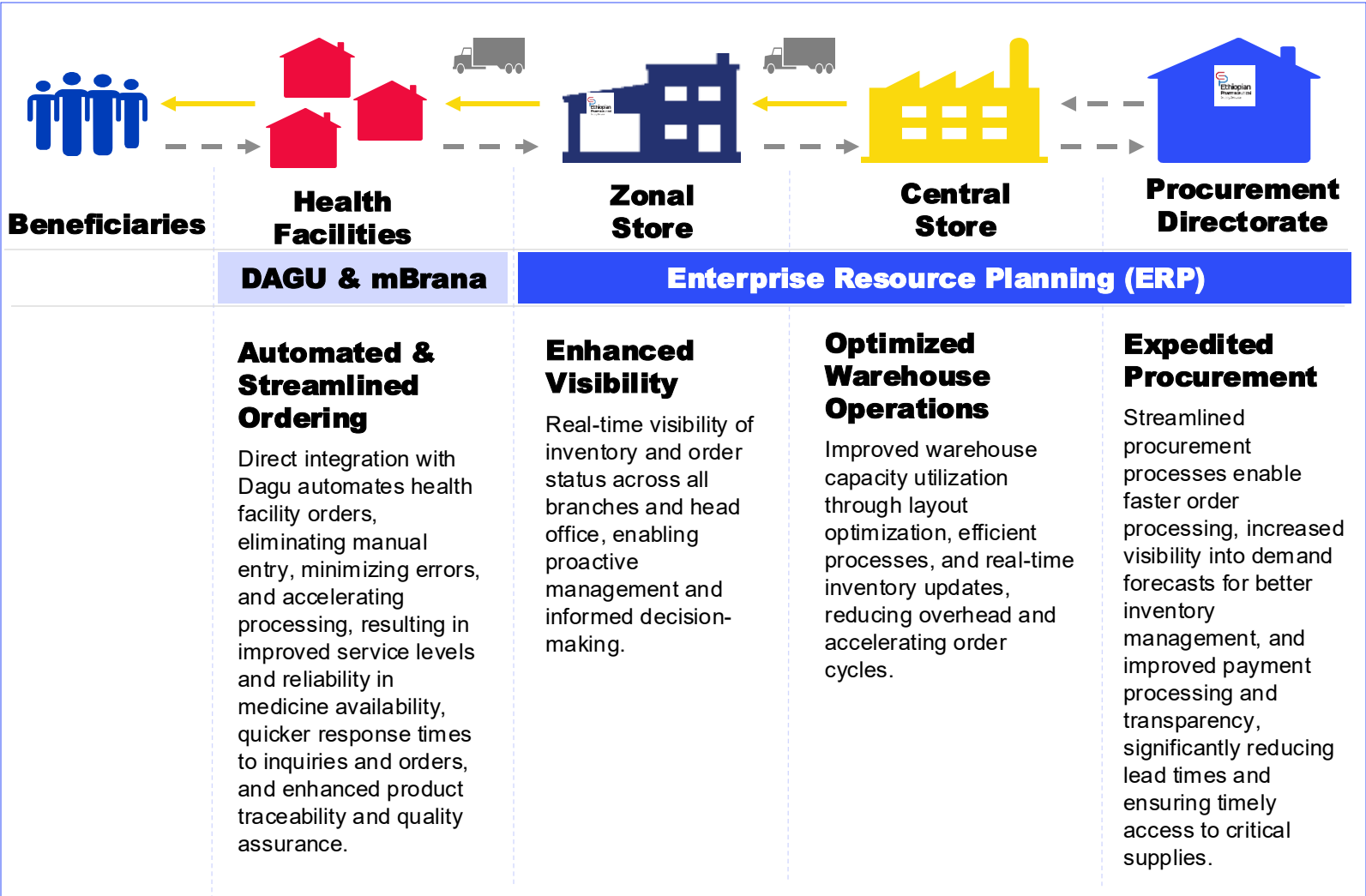
Consolidated System

- Replaces 10+ disparate systems with a single, integrated platform, eliminating duplicate systems and their associated costs
- Estimated ROI of US\$9.8 million in 3 years

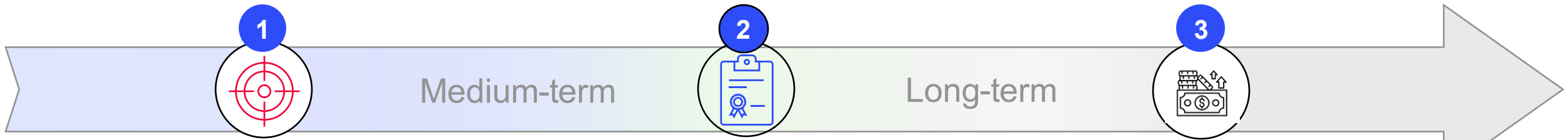
Automation & Efficiency Gains

Significant process automation enabling \$277M in sales since May 2024 :

- Finance: 90% fully automated, 10% partially automated processes
- Supply Chain: 76% fully automated, lead time for order processing has reduced from 4.5 to 2.1 days
- Human Resources: 57% fully automated



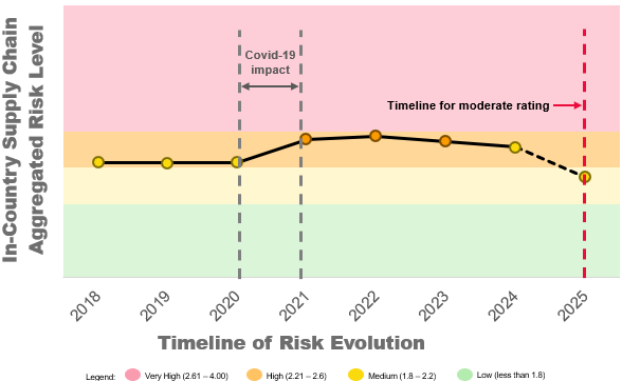
Addressing in-country supply chain risks while supporting system maturity enhancements to sustain progress and maximize outcomes



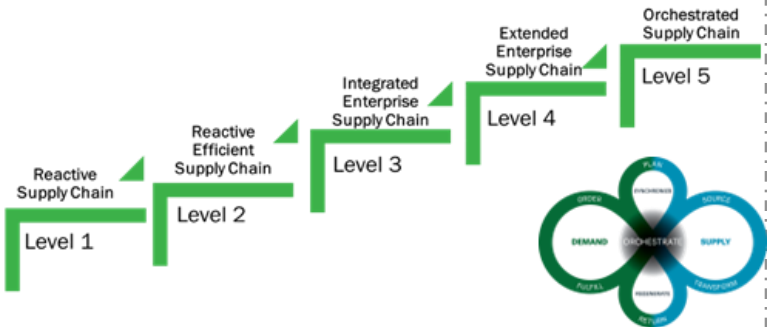
Focus on 15¹ priority countries by implementing tailored efficiency and risk mitigation strategies to achieve moderate risk levels by end of 2025, These include:

- i. investments in efficiency opportunities, infrastructure, operations improvement and information systems;
- ii. conducting standardized assurances;
- iii. ensuring routine performance monitoring

In-country supply chain risk overview



Conduct the **Global Health Supply Chain Maturity Model** assessments in High Impact and Core countries to evaluate the maturity of key processes, metrics and strategic enablers to enable more effective, efficient and sustainable supply chains.



Strengthen **collaboration with countries and partners on sustainable supply chain transformation** with key priorities including:

INNOVATION

Focusing on innovations that have high-potential to expand access, affordability, availability and quality of care and health products

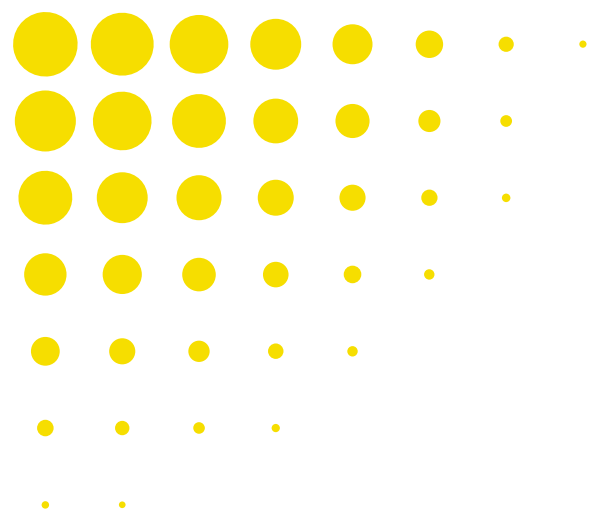
STEWARDSHIP

Fostering ownership accountability, financing and functions, and in doing so, enhancing efficiency, ensuring robust processes and integrated digital systems -

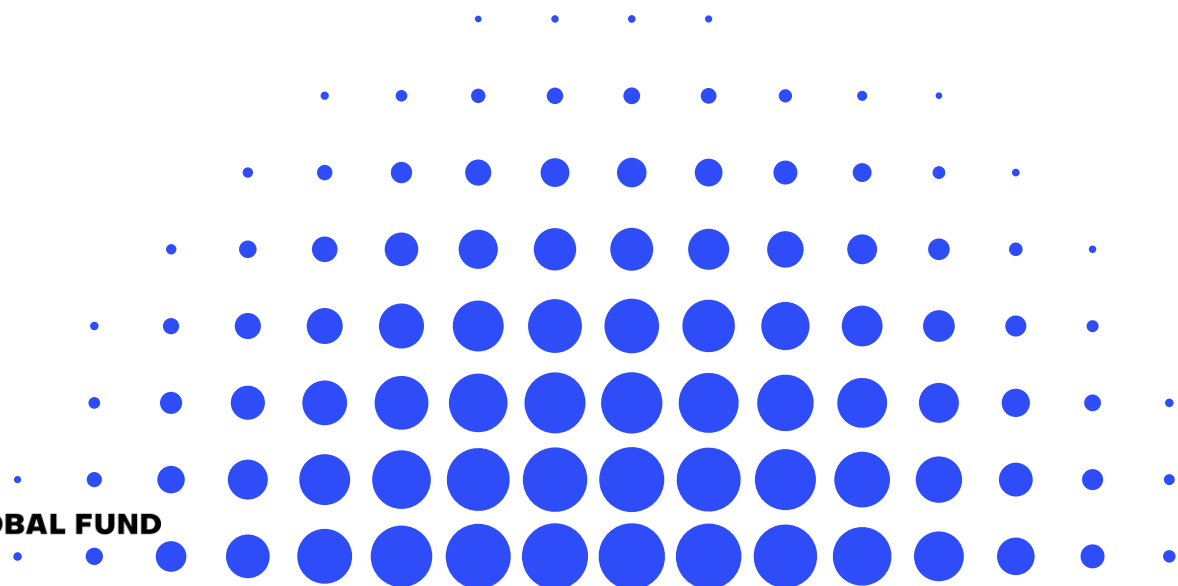
PEOPLE CENTRICITY

Prioritizing the needs and experiences of clients in every aspect of decision-making, impacting both patient care and operational efficiency

(1) Angola, Burkina Faso, Cameroon, Central Africa Republic, Chad, Côte d'Ivoire, Congo (Democratic Republic), Eswatini, Ghana, Guinea-Bissau, Haiti, Liberia, Mozambique, Nigeria, Sudan.



Annex 3: Relevant Past Board Decisions

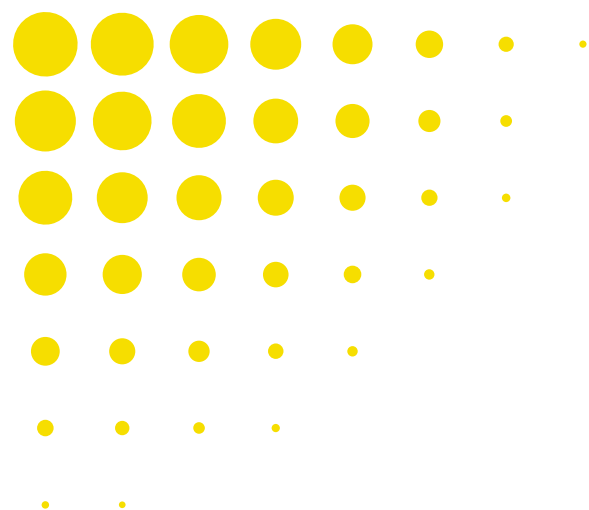


Annex 3: Relevant Past Board Decisions [1/2]

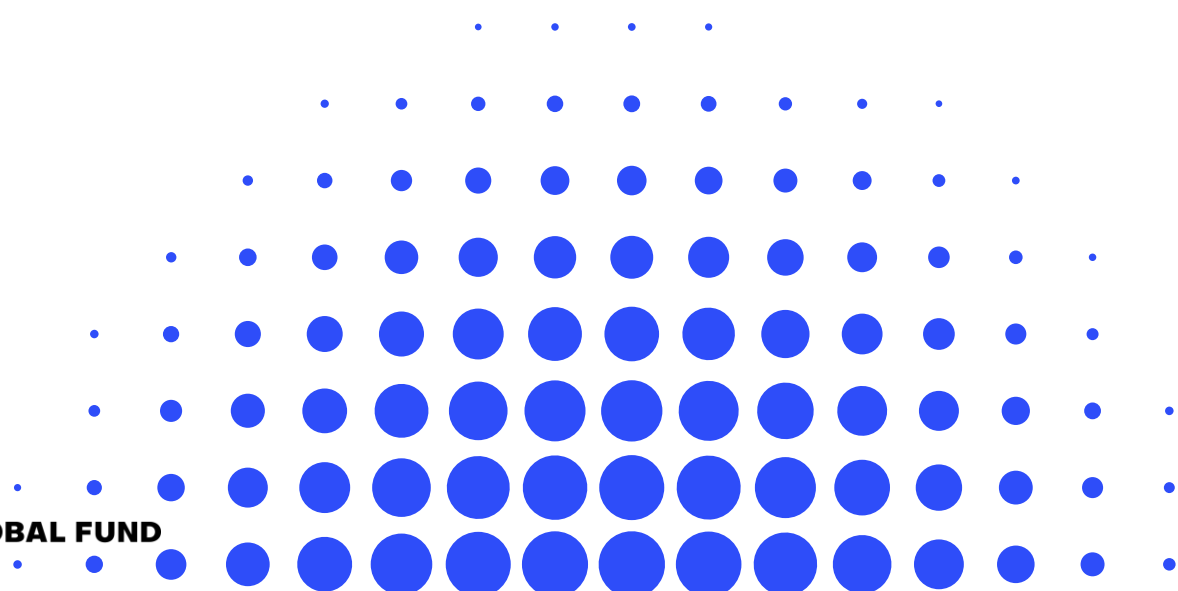
Relevant Past Decision Point	Summary and Impact
<u>GF/B51/DP03 Quality Assurance Policy for Vector Control Products</u> (April 2024)	<p>Based on the recommendation of the Strategy Committee, the Board approved the Quality Assurance Policy for Vector Control Products and Related Equipment. It requested the Secretariat to work with the World Health Organization (WHO) to establish an Expert Review Panel for Vector Control Products and to conclude the necessary arrangements with WHO. It also delegated authority to the Secretariat, in consultation with the Strategy Committee Chair and Vice Chair, to make non-material adjustments to the Policy and to report back to the Strategy Committee and Board on all such changes.</p> <p>Additionally, while the Board expects efforts will be made to fully implement the Policy upon its approval, the Board noted that implementation of certain aspects of the Policy would require a reasonable transition period.</p>
<u>GF/B51/DP04 Global Fund Procurement Policy Update</u> (April 2024)	<p>Based on the recommendation of the Audit and Finance Committee, the Board approved an updated Procurement Policy which sets out principles that govern the procurement of goods and services by the Global Fund. The Board delegated authority to the Executive Director for operationalization of the Policy and requested annual updates from the Secretariat reporting on its operationalization. The Board asked the Secretariat to work with the Audit and Finance Committee to agree on the appropriate content for these updates.</p>
<u>GF/B50/DP06 Amended and Restated Global Fund Quality Assurance Policy for Pharmaceutical Products and Amended and Restated Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment</u> (November 2023)	<p>Based on the recommendation of the Strategy Committee, the Board approved:</p> <ol style="list-style-type: none">1. the Amended and Restated Quality Assurance Policy for Pharmaceutical Products; and2. the Amended and Restated Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment, which replaces in its entirety the former Quality Assurance Policy for Diagnostics Products. <p>The Board delegated authority to the Secretariat, in consultation with the Strategy Committee Chair and Vice Chair, to make non-material adjustments to these two quality assurance policies and to report back to the Strategy Committee and Board on all such changes.</p>

Annex 3: Relevant Past Board Decisions [2/2]

Relevant Past Decision Point	Summary and Impact
<u>GF/B48/DP07: Advancement of Non-Global Fund-Financed Procurement Utilizing the Pooled Procurement Mechanism and wambo.org (November 2022)</u>	Based on the recommendation of the Strategy Committee (GF/SC20/DP03), the Board approved the Secretariat's continued operationalization of the current scope of non-Global Fund-financed orders by governments and non-government development organizations in Global Fund-eligible countries, for products and services on wambo.org, removing any cap, with reporting on the non-Global Fund-financed procurement integrated into annual updates to the Board on NextGen Market Shaping implementation.
<u>GF/B17/DP21: Transition from Administrative Services - Human Resources and Financial Rules (April 2008)</u>	The Board requested the Finance and Audit Committee (FAC) to invite all interested Board constituencies to participate in preparation of the HR Policy to remain in effect at the end of an interim period, linked to the transition from the Administrative Services Agreement with WHO. In addition, the Board delegated limited authority to the FAC to approve an interim HR policy applicable to the interim period and the initial rules applicable to the purchasing of services and goods and non-grant financial management.
<u>GF/B15/DP15 Market Dynamics and Voluntary Pooled Procurement (April 2007)</u>	The Board approved the establishment of a pooled-purchasing service whereby payments are made to procurement agents for target products. [Today it is referred to as the Pooled Procurement Mechanism.]



Annex 4: Relevant Past Documents and Reference Materials



Annex 4: Relevant Past Documents and Reference Materials

- Quality Assurance Policy for Vector Control Products and Related Equipment, GF/B51/05 (April 2024)
- Global Fund Procurement Policy Update, GF/B51/20 (April 2024)
- Global Fund Quality Assurance Policy Updates: Pharmaceutical Products and Medical Devices, including In-Vitro Diagnostics, and Core Personal Protective Equipment, GF/B50/05 (November 2023)Drive equitable access to quality assured health products through NextGen Market Shaping, GF/B48/11 (November 2022)
- Non-Global Fund-financed procurement through wambo.org, GF/B48/05 (November 2022)