

Drive equitable access to qualityassured health products through NextGen Market Shaping

48th Board Meeting GF/B48/11

15-17 November 2022, Geneva



Executive Summary

Context

- 1. To deliver on the ambition of the 2023-2028 Strategy, which is an enabler to accelerate progress towards global goals together with all the stakeholders involved, a NextGen Market Shaping approach has been developed to drive equitable access to quality-assured health products.
- Health products for diagnosis, prevention and treatment are critical for ending the three diseases, and the Global Fund is a key player in global health product markets.* The Secretariat supports countries to access quality products for communities and people in need, with approximately half of health product demand being channeled through its Pooled Procurement Mechanism (PPM)/wambo.org.
- 3. The Board is receiving the Global Fund's NextGen Market Shaping update following the discussion at the Board retreat in July 2022 and input from the Strategy Committee. This update also includes the Strategy Committee's recommendation for the non-Global Fund-financed procurement mechanism through PPM/wambo.org.

Questions addressed in this slide deck

- 1. What is the current status of NextGen Market Shaping interventions and how do they build on lessons learned and partnership efforts?
- 2. How will NextGen Market Shaping interventions integrate key health product-related risk considerations and mitigations?
- 3. What are the proposed next steps, including for the non-Global Fund-financed procurement mechanism through PPM/wambo.org?

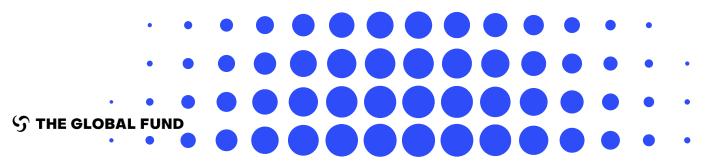
Input Received – Strategy Committee discussions (SC17, SC18, SC19 and SC20), including on the TERG Position Paper on the evaluation of the wambo.org pilot on non-grant orders; Audit and Finance Committee discussions (AFC17 and AFC19); and Board retreat (July 2022).

Input Sought – The Board is requested to: (i) review this update and provide input on the NextGen Market Shaping approach; and (ii) make a decision on the non-Global Fund-financed procurement mechanism through PPM/wambo.org (See <u>GF/B48/05</u>.)

S THE GLOBAL FUND *Annual health product investments are approximately USD 2 billion, and approximately USD 3 billion including COVID-19 health products. 2

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 - C Non-Global Fund-financed Procurement Mechanism: Secretariat's proposed way forward





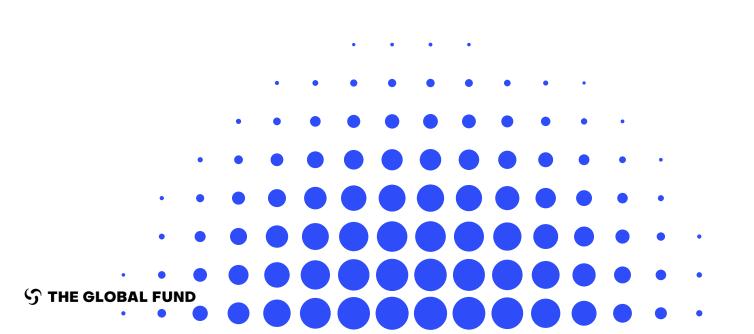


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Overview of 2021 Achievements

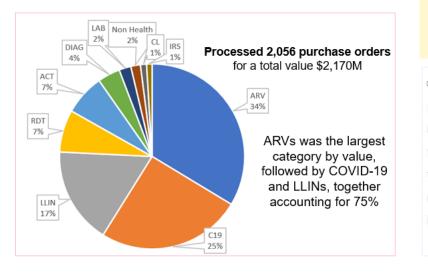
Strategic achievements for PPM

Management of market access through longterm framework agreements for pooled procurement volumes continues to yield improvements in **availability** and **affordability**

- Reliable On-Time In-Full delivery (Supplier OTIF): 87-94% across key product categories
- Faster emergency order responsiveness for select product categories: 40% improvement since 2016
- Price reductions over time without supplier exit: 32-37% price reduction on key products over past 3-5 years

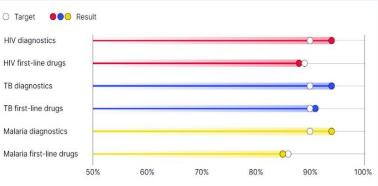
Procurement / wambo.org platform

Orders processed* and 5,000 shipments tracked from manufacturing to delivery, with overall user satisfaction favorable at 91%.



On-shelf availability of tracer products

- For the six product categories, product availability at the heath facility level was close to or exceeded the target that had been set.
- Continued focus on supply chain strengthening to ensure sustained results.
- Cohort has been expanded to 45 countries to be reported quarterly through spot checks.



Looking ahead

Harnessing the power of partnerships to drive equitable access to quality assured health products while mitigating key challenges

Key Challenges

Ongoing global supply chain disruption and pressure on the cost of health products and services linked to:

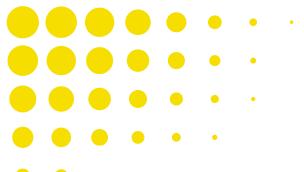
- 1. Higher energy costs
- 2. Inflation/recession
- 3. Exchange rate fluctuations
- 4. Political instabilities
- 5. Climate impact

Way forward, at lower funding level...

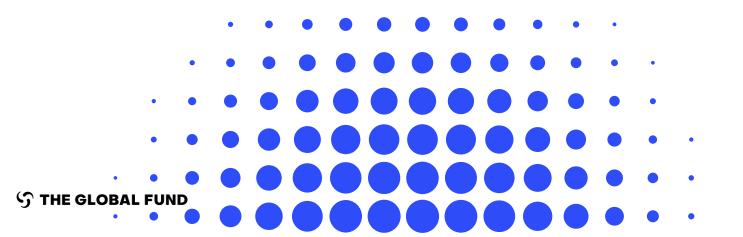
Key Opportunities

Multilateral partnership collaboration for access to innovation and system strengthening

- 1. Complementary and cross-cutting approach
- 2. Aligned prioritization approach for best use of resources across the ecosystem
- 3. Inclusiveness and community engagement
- 4. Country access to well-established global and regional procurement platforms
- 1. Approach systems strengthening and innovation in a symbiotic and complementary way to sustain the 3 disease outcomes and impact of the investments
- 2. Continue to align and prioritize across NextGen, RSSH, cross-cutting and disease-specific catalytic interventions
- 3. Need to find creative solutions and continue to leverage partners' work
- 4. Continue to provide countries with options to access quality assured and affordable health products reliably and efficiently



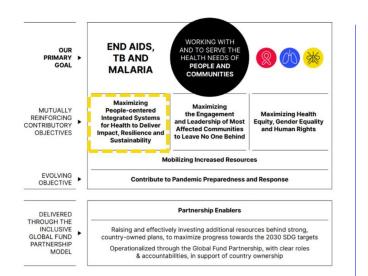
- B Update on NextGen Market Shaping Approach
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 - **3** Sustainable procurement and country capacity building
 - PPM/wambo.org and networked global and regional procurement platforms





The 2023-2028 Strategy and NextGen Market Shaping

Harnessing the power of partnerships to drive equitable access to quality assured health products

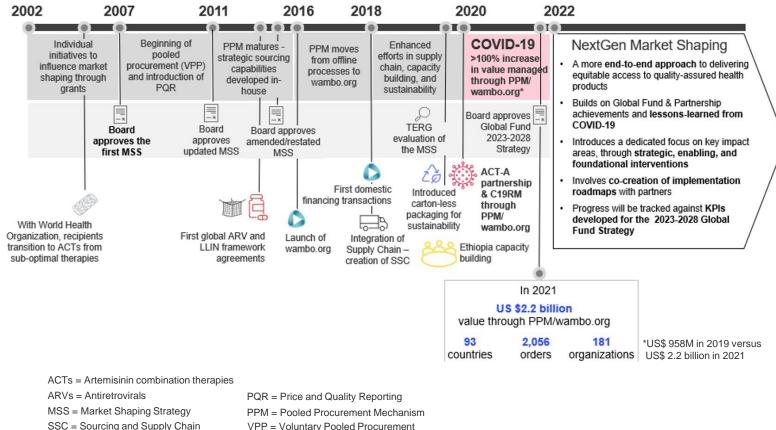


The 2023-2028 Strategy lays out the strategic direction for *Maximizing People-Centered Integrated Systems for Health to Deliver Impact, Resilience and Sustainability*.

The NextGen Market Shaping approach is designed to operationalize this direction across a number of the 10 key changes.

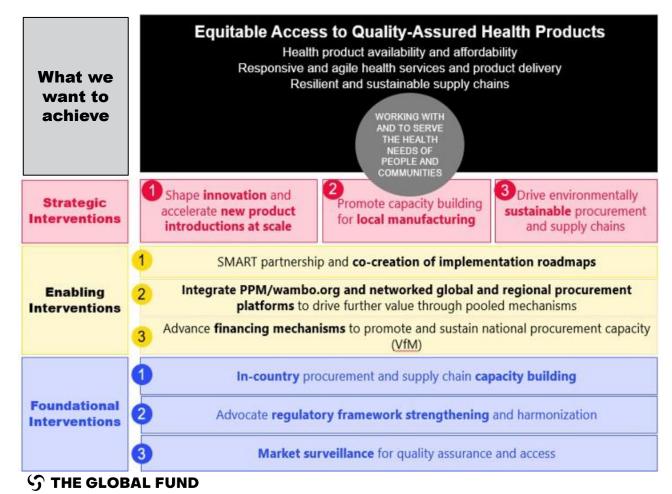
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The Global Fund is a key player in global health product markets and is **well placed** to play a **deliberate and strategic role** to **shape global markets alongside partners** to **strengthen the impact of HTM programs** and **ensure quality-assured medicines and other health products** are **available** to those who need them.



NextGen Market Shaping interventions to strengthen people-centered health systems

Market shaping efforts are needed to ensure availability and affordability of quality-assured health products delivered to those who need them in an efficient, reliable and timely way. This requires a set of strategic, enabling and foundational interventions to maximize value for money on health product investments while mitigating market risks, driven by demand, supply and other factors.



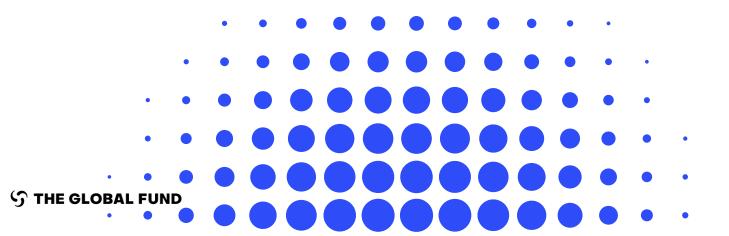
Key messages

The focus of NextGen Market Shaping is aligned to the ambition set out in the Global Fund's 2023-2028 Strategy.

- The NextGen MS framework outlines specific interventions, focusing on equitable access to quality-assured health products and services.
- NextGen MS approach includes a holistic set of programmatic driven interventions **oriented around the people and communities we serve.**
- In-country capacity building, regulatory framework strengthening, and market surveillance remain critical foundational interventions to sustain the progress in building more robust and resilient national and community health systems.
- SMART partnership co-shaping and harnessing C19RM lessons learnt will help us in the fight of HIV, TB and Malaria.

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For Input: Accelerating health product introductions at scale [1/7]

Harnessing Global Fund's partnership approach to drive accelerated health product introductions at scale

Co-convening Partnership Task Force with *Volitaid*

Input	Key activities aligned with our comparative advantage	Intermediate Long-term Impact
Co-financing & partner investment to meet vast needs Catalytic investment to support supply readiness	Upstream (innovation) Monitor landscape and invest in most promising products; Support clinical trials to assess and collect data for policy changes; Leverage scale and position as a large public sector investor in health products to co-define our pipeline priorities with key partners and crive these priorities across the partnership Evidence- based Unitaid Upstream People & community-centered	Reduced time to introduce and scale prioritized health products to meet the needs of people & communitiesReduced morbidity and mortality through better prevention, diagnostic, and treatment outcomes
Grant investment to support country-readiness	Midstream (access)Downstream (scale)Leverage relationships with industry and strategic sourcing capabilities to incentivize innovation. Develop financing mechanisms & market shaping interventions to secure supply, support accelerated regulatory pathways, and sustainably drive affordability.Downstream (scale)Midstream (access)Support country-readiness through strengthened operational guidance and technical support on new product introduction, leveraging our country-led, CCM-driven model & grant lifecycle processes	 Contributory outcomes Greater Value-for-Money for health product investment Enhanced partnership roles and accountabilities Maximized People-Centered, Integrated Systems for Health to deliver impact, resilience, sustainability

For Input: Accelerating health product introductions at scale [2/7] Accelerate health product introduct introductions at scale

Work is in progress both across the Secretariat and the broader partnership, drawing on lessons learned to accelerate equitable access to quality assured health products

At the Secretariat

 Technical Information Notes for 2023-2025 developed including mention of pipeline products.
 Preliminary workplan developed.

Steps

Next

- 1 Establishment of a cross-department Management Committee.
- 2 Development of a New Product Introduction "Playbook": enhanced guidance for new product introduction and transition. This will be incorporated into an update to the Operational Policy Note.
- 3 Assess key risks associated with accelerated HPI at scale.

New Product Introduction Pilot

Explore financing mechanisms **to address key market barriers** with support from partners. This may include a revolving fund mechanism for potential advance market commitment. Disease-specific product pipeline mapping and prioritization efforts with partners.

Across the partnership

- Co-convening with Unitaid a Partnership Task Force.
- 2 Transparency on disease-specific product pipeline and prioritization, informed by partner input.
- Hold initial Partnership Forum on 21
 October 2022.
- 2 Development of implementation roadmaps with partners, by sub-groups.
- 3 Development of Catalytic Investment Cases for Strategic Initiatives: Both disease-specific and market-facing strategic initiatives.

Partnership Task Force

Partners (technical partners, scale up partners, implementation partners, etc.); Donors; Communities living with the diseases & CSOs; and Countries

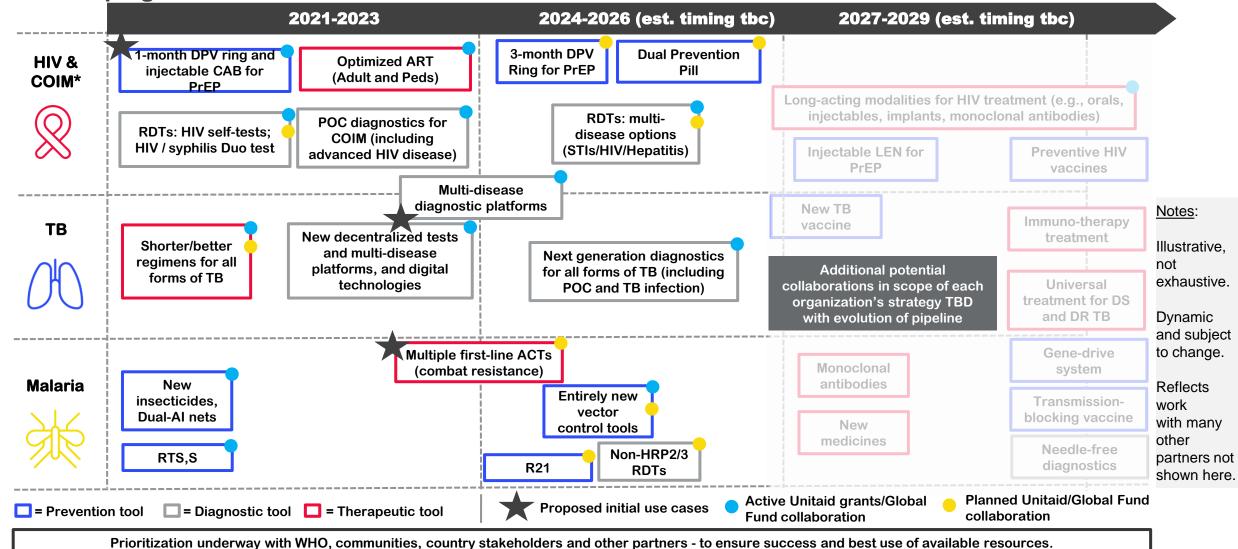
Current status

Next Steps

For Input: Accelerating health product introductions at scale [3/7]

Progress on prioritization of product pipeline

The Global Fund and Unitaid have mapped the product portfolio and consulted with other relevant partners for additional input. Prioritization efforts underway with Unitaid through the Partnership Task Force to inform market shaping interventions.



Not shown: Unitaid programs in cervical cancer screening and tools for treatment of precancerous lesions, tools for advanced HIV disease, tools for harm reduction among Persons Who Inject Drugs *COIM = Co-infections and co-morbidities.

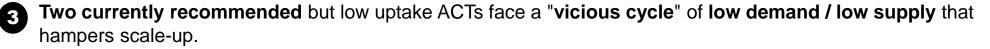
For Input: Accelerating health product introductions at scale [4/7]

Deliverables

USE CASE Biological threats to malaria case management in Africa

Key challenges to be addressed Levels of resistance to ACTs increasing in Africa; no new products are expected before 2026.

Therapeutic lifespan of current ACTs can be extended by diversifying ACT portfolio in countries.



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An urgent market intervention is needed to address this and save lives until newer products are available.

Workstream

0	Country implementation framework	Provide a framework to support countries in selecting, prioritizing and implementing WHO-recommended interventions in their specific context	Country implementation framework
2	Regional initiatives resistance surveillance	Define an investment plan to address priority challenges in malaria resistance surveillance, leveraging \$20m earmarked for "addressing biological threats in casemanagement"	Concept note formalizing Global Fund's investment plan
3	Market-shaping interventions on Malaria	Define an investment plan to address antimalarial drug resistance by scaling access to non-AL/ASAQ ACTs, leveraging market-shaping catalytic funding	Investment plan for market-shaping Inputs on sizing of innovative financing facility
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Key objectives

NextGen Market Shaping Catalytic Investment

For Input: Accelerating health product introductions at scale [5/7]

USE CASE

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Accelerating access to new PrEP products PrEP ring (DPV-VR) and injectable PrEP (CAB-LA)

Key challenges to be addressed New PrEP products are costly, have unique implementation considerations, and risk being overly medicalized Activities for HIV prevention product introduction are often considered lower priority and often unfunded Current products aren't meeting client needs– clients need choice of product and where they receive services Countries are not well prepared to set targets, cost programming, or quantify commodity needs for PrEP options

Workstream

Key objectives

Current funding cycle

Preparing for the next funding cycle

Prepare countries with first regulatory submissions for product introduction across product introduction value chain

Provide framework to support countries to select, prioritize and implement focal activities re: PrEP ring and injectable intros, ensuring clients are provided product choice and reached through innovative & varied service delivery channels

Support country level target setting, program costing, and commodity forecasting for new prevention products

Long-Acting PrEP: Coalition (next slide); <u>PrEP ring</u>: explore opportunities to lower price (e.g., subsidies, volume guarantees)

Deliverables

At least two countries with product delivered and national guidelines for PrEP updated by EOY. Dedicated PrEP and Prevention Product Introduction Advisor with TAP HIV Team.

Activities for new prevention product introduction shared with CTs, building on additions to HIV information note already published.

Dedicated Prevention Systems Advisory in RSSH.

Co-facilitation of training organized by UNAIDS and MOSAIC (funded by USG) with representatives from 15 countries being trained on target setting, program costing and commodity forecasting for PrEP products

See next slide for outcomes of Coalition on Long-Acting PrEP Identification of MS initiative proposal for PrEP ring to lower cost

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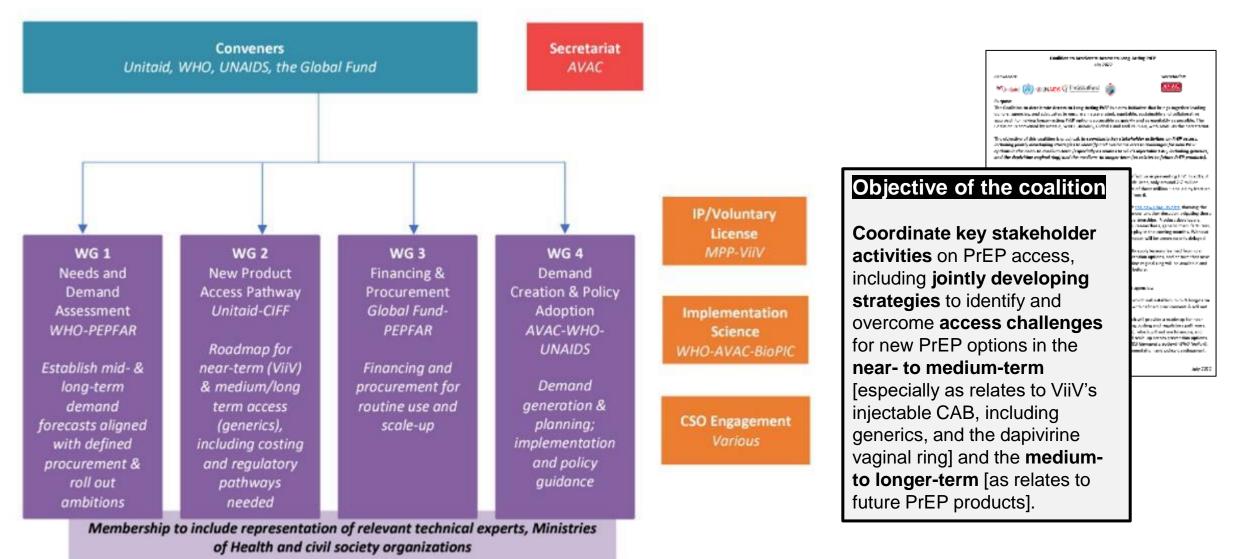
Market-shaping

interventions on

HIV prevention

Coalition for LA PrEP

Leverage Task Force to enhance broader partnership engagement



USE CASE TB diagnostic testing

Key challenges to be addressed	Near monopoly market for WHO-recommended rapid molecula Fit-for-purpose, fit-for use options for diagnostic tools are need Opportunity: TB diagnostic pipeline has several diagnostic tech Product Profiles approaching marketing approval with potentia grant cycle Action is needed now to ensure country readiness to procure a diversity and competition to the TB diagnostic space.	led to accelerate case-finding efforts nnologies fulfilling aspects of the WHO Target I to enter process for normative guidance for next
Workstream	Key objectives	Deliverables
1 Country Readin for Innovation	ess Leverage Matching Funds approach to shorten the time to policy adoption of new diagnostic tools and ensure successful pilot projects and/or new	Appay to Clobal Fund quidance note to countries

Provide targeted TA to support the implementation of country readiness activities for the introduction and scale up of new TB diagnostics

guidelines move to national scale up in a timely

Annex to Global Fund guidance note to countries with an outline of proposed activities for country readiness for new diagnostics and TA available to implement/address challenges

Market-shaping interventions on TB

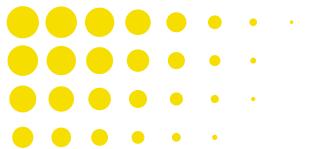
Define an investment and implementation plan to complement partner efforts, leveraging market-shaping catalytic funding

Investment plan for market-shaping

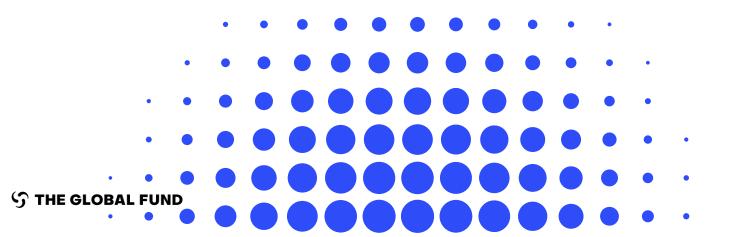
Inputs on sizing of innovative financing facility

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manner.



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Leveraging Global Fund's comparative advantage to promote local manufacturing capacity building to achieve equitable access to quality assured health products

				Not exhaustive				
Ambitions	Inputs	Key activities aligned with our comparative advantage	Intermediate outcomes	Long term outcomes	Impact			
	Priority bottlenecks to be addressed from a landscape analysis	The Global Fund should leverage its comparative advantages including Country-led model and inclusive partnerships with countries, global/regional partners & the private sector, for promoting alignment and robust technical support	comparative advantages includingAdditional updates to Secretariat PPM tender processes andIncreased regional harmonization of regulatory					
Drive equitable access to quality-	and product portfolio mapping: 1) lack of industry knowledge, resources,	Long experience fighting the 3 diseases through evolving approaches building on lessons learned	promote local manufacturing.		More equitable			
assured health products by	infrastructure; 2) lack of national policies in creating	Market intelligence / experience in the health product industry, and long existing supplier relations	Ь	Ь	access to quality assured health products to meet the			
promoting capacity-	enabling environments; 3) weak regulatory frameworks and lack of harmonization.	Large procurement scale (USD 2b annual through PPM) and relations with big buyers; leverage for market shaping	Clear-cut implementation roadmap (e.g., high	Increased share of locally manufactured	needs of people & communities.			
building for local	255	to drive the following targeted capacity building areas:	priority products identified) developed	health products and higher share of				
manufacturing and increasing	Partnership collaboration	• additional cumplions lowersging Clobal Fund tenders		quality assured manufacturers of key HTM products	~~~			
resilience and responsiveness of	to explore a complementary / coordinated approach with	2 Support regional regulatory framework strengthening and harmonization		in LMIC.				
global & regional	partners and to avoid duplication of efforts.	3 Engage with regional procurement platforms and consortiums to increase sustainable capacity		<u> </u>	Reduced morbidity and mortality from			
health supply chains.	(b)	Build inter-agency efforts and partner and country engagement to identify key priorities	Initial technical assistance offered for capacity building for	C Sustainable and	resilient supply chains that continue			
	Catalytic investment	5 Support accelerated product qualification and country demand forecasting	framework strengthening and	transparent long- term demand for	to provide critical health products			
	to create enabling environments for quality- assured, local production	6 Advocate for technology / "know-how" transfer amongst global and local manufacturers	quality compliance.	local products.	despite global disruptions. 1			

Capacity building for local manufacturing

Work is in progress to identify priority areas and explore partnership opportunities

At the Secretariat

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Next Steps

(3)

- 1 Initial landscape analysis underway to identify key bottlenecks and focus areas.
- 2 Initial adjustments made to PPM tender processes and internal procedures to further incentivize local manufacturing and market engagement.
- 1 Create baseline mapping of local manufacturing for GF product portfolio.

2 Identify priority areas to focus efforts on interventions / initiatives, incl. e. g., update procurement and QA policy to further incentivize for local manufacturing.

Assess key risks and develop mitigation approach to address risks associated with local manufacturing capacity building.

2020 % of volume share through PPM

- 11% of LLIN volumes manufactured in Africa
- 70% of essential medicines supplied by sub-Saharan manufacturers*
- 18% of total artemether-lumefantrine supplied by sub-Saharan manufacturers

sources

Identify

high-priority

products for

expansion from

existing local

manufacturing

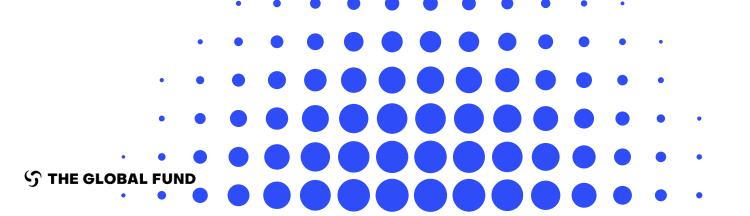
Across the partnership

 Initial conversations held with partners (e.g., USG, FIND, Gavi, IFC) to explore opportunities for partnership efforts; further alignment ongoing.

Current status

- Explore a closer partner collaboration, including regional partners, supported by technical organizations, depending on areas of capacity building identified.
- 2 Development of Catalytic Investment Case for the Strategic Initiative.

- B Update on NextGen Market Shaping Approach
 - Accelerating health product introductions at scale
 - Capacity building for local manufacturing
 - Sustainable procurement and supply chain (Strategic Intervention) and in-country country capacity building (Foundational Intervention)
 PPM/wambo.org and networked global and regional procurement platforms



Leveraging Global Fund's comparative advantage for in-country capacity-building to drive sustainable procurement and supply chains

			Not exhaustive								
Ambitions	Inputs	Key activities aligned with our comparative advantage	Short-term outcomes	Intermediate outcomes	Long term outcomes	Impact					
Targeted investments in RSSH HPMS Incentivize investments in RSSH Health Product Management Systems by countries through	Global Fund Strategy Guiding principles from the new 2023-2028 Strategy PSM experience and progress	Targeted capacity building areas: a Sourcing and Procurement National and regional procurement platform capacity building, collaboration and knowledge sharing	 Other buyers can access advantageous PPM Framework terms and conditions b Strengthened 	a Skills and knowledge transfer to enhance national and regional procurement processes: skills, tools and availability of market information	Improved availability of commodities through						
Matching Fund Mitigate risk level Focus targeted efforts in high-risk countries to achieve a moderate	Experience, lessons learned and existing progress from Procurement and Supply Management (PSM) Strategic Investments over previous two cycles	Health Product Quality Assurance Pharmacovigilance and market surveillance, including in-country quality assurance capacity assessment and technical support	regulatory information system, improved NRA supervision of storage and distribution	b Increased capacity of NRAs & regulatory information systems; improved efficiency and consistency of regulatory operations	efficient supply chain operations measured by on-shelf availability	Reduced morbidity					
overall procurement, QA and supply chain (SC) risk level	Areas for investment: All PSM investments including Matching funds	Supply chain Sustainable Supply Chain Governance: master plan and HRH policy development, performance-based	Improved workforce and stakeholder capacity to govern supply chains	C Effective governance systems that drive improved accountability	Dimproved product and patient safety through	and mortality through equitable access to quality assured health					
Supply chain and quality assurance maturity Assess current supply chain and quality assurance (QA) maturity to conduct targeted interventions	and grant funds	financing, SC workforce assessment, <i>ii. <u>Data-driven supply chains</u>:</i> Master data mgmt. and data standards, HMIS-LMIS	Efficient, data driven supply chain operations	and planning Supply operations run by comprehensive data	strengthened National Regulatory	products					
	Country stewardship: Continued and increased collaboration and partnership with in- country stakeholders and partners	interoperability <i>iii.</i> <u>Supply chain design</u> : Alternative distribution models into communities, warehouse operations improvement <i>iv.</i> <u>Outsourcing</u> : Outsourcing management and governance, improvement of means to access logistics service providers, improvement of logistics market	More efficient supply chain warehousing and distribution operations Strengthened management of outsourced logistics services	reported from health facilities measured by LMIS reporting rate More effecient warehousing and distribution functions measured by On-time-in-	Authorities (NRAs) and regulatory systems						
HMIS: Health management inf	ormation systems HRH: Huma	n resources for health LMIS: Logistics managemer		full (OTIF) rates and SATP	lan	2					

For Input: Sustainable procurement and supply chain [2/3]

In-country capacity building to drive sustainable procurement and supply chain

At the Secretariat

- 1 Drawing lessons learned from ongoing Strategic Initiatives to develop integrated and end-to-end plans.
- 2 Cohort of countries being defined for alignment on scope.
- Next Steps
- 1 Establish a clearly aligned plan with Grant Management at the portfolio level and integrated approach with RSSH interventions at the country level to address foundational areas.
- 2 Assess key risks and develop mitigation approach to address risks associated with in-country capacity building.

Accelerate incountry capacity building through increased country engagement, ownership and accountability

Across the partnership

- Continue to consolidate lessons learned, including from implementation of the current PSM Transformation Strategic Initiative and Quality Assurance Strategic Initiative.
- Matching Funds for country-specific interventions integrated into grants.
- 2 Development of Catalytic Investment Case for Strategic Initiative funds for cross-cutting Secretariat-led interventions at global/regional levels.

Key areas of focus

Sourcing and procurement

National and regional procurement platform capacity building, collaboration and knowledge sharing. **Quality assurance**

Pharmacovigilance and market surveillance, including in-country quality assurance capacity assessment and technical support.

In-country supply chain

Governance, information systems, optimized warehousing and private sector partnerships for logistics solutions. Current

Next

Steps

status

Foundational interventions set out in NextGen Market Shaping address key risk areas

In-country capacity building, regulatory framework strengthening and market surveillance

Interventions

Key

Procurement Management

Procurement challenges and failures could lead to poor value for money or financial losses, incorrect or sub-standard products or delayed delivery, potentially leading to stock out, treatment disruption; poor quality of services or wastage of funds or products.

Quality assurance of health products

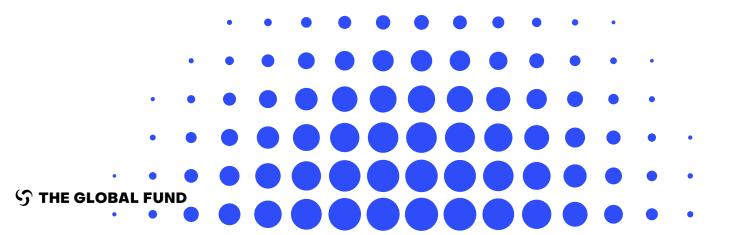
Patients exposed to health products of substandard quality; i.e., health products (purchased by Global Fund-supported programs) that are not safe, effective and/or of good quality.

In-country Supply Chain

Disruption or poor performance of in-country supply chain, from central warehouse to point of service delivery that could result in inadequate availability of commodities and/or wastage of grant-funded commodities through expiries or diversion, impacting the achievement of grant objectives.

- Enhance second line functions on procurement and supply chain management policy, advisory and monitoring, alongside Finance and Risk.
- 2. Enhance data **analytic capabilities** through integrated **monitoring** and **reporting** approach.
- 3. Strengthen exception and incident management and knowledge transfer.
- 4. Enhance **procurement and supply management guidance** as part of modular framework for grant performance monitoring.
- 5. Develop **country-specific action plans** and provide **technical support** to countries in collaboration with GMD, focusing on countries with high and very high-risk profile.
- 6. Ensure aligned RSSH approach and sufficient investment made for in-country capacity building through **Catalytic Investments**, including **Matching Funds through grants**.

- B Update on NextGen Market Shaping Approach
 - Accelerating health product introductions at scale
 - Capacity building for local manufacturing
 - Sustainable procurement and country capacity building
 - **OPPM/wambo.org and networked global and regional procurement platforms**





For Input: PPM/wambo.org and networked global and regional procurement platforms [1/2] PPM/wambo.org and networked global and regional procurement platforms to drive value and equitable access to quality-assured health products

Global Fund 2023-2028 Strategy

 Maximizing People-centered. Integrated Systems for Health to Deliver Impact, Resilience and Sustainability.

NextGen Market Shaping Equitable access to quality-assured health products, grantfunded and non-grant funded.

Mobilizing increased resources.

Health Financing

Increased focus on value for money; Support country health financing systems to improve sustainability.

 Contribute to pandemic preparedness and response. Remain agile to respond directly to the rapidly evolving global health context.

What is needed by countries?

Well-developed, well-managed national procurement mechanisms also with access to regional and global pooled procurement platforms.





🖏 National levels

Complementarity of Global (G), Regional (R) and National (N) procurement platforms

= PPM/wambo.org

Global Fund's PPM/wambo.org continues to be an enabler for strengthening the capacity of regional and national procurement channels



PPM/wambo.org mechanism to allow country access to quality-assured health products through a diverse set of global pooled mechanisms (e.g., UNOPS, UNFPA, UNICEF).



Use PPM/wambo.org to drive collaboration with regional platforms, such as accessing Global Fund's long-term framework agreements, including joint tender approaches (e.g., PAHO).



Continue to provide access to Global Fund's long-term agreements and knowledge sharing for countries for both grant and nongrant funded procurement (e.g., Kenya Medical Supplies Authority/KEMSA, Ethiopian Pharmaceuticals Supply Platform/EPSA). **26** For Input: PPM/wambo.org and networked global and regional procurement platforms [2/2]

Partner with regional procurement platforms to strengthen country capacity and access

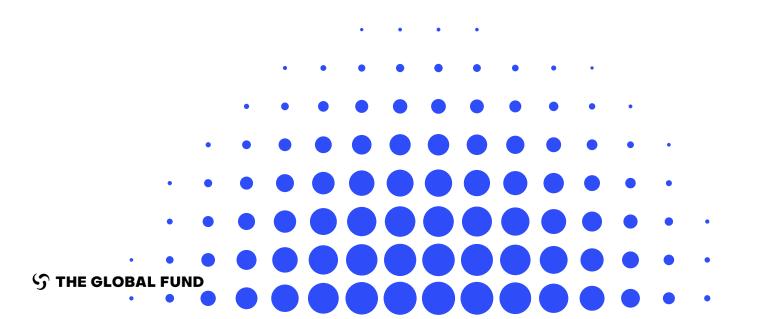
Effective collaboration and coordination will enable the extension of impact of buying power and support market sustainability across greater volumes



risk management.



C Non-Global Fund-financed Procurement Mechanism: Strategy Committee's recommendation on the way forward



Non-Global Fund-financed procurement: pilot

Making options available to countries for value for money on health product investments can enhance impact, sustainability and successful transitions from Global Fund financing.

Why has the pilot for non-grant orders been implemented?

To enable countries with additional access to quality-assured health products for eligible buyers using non-Global Fund grant funds and provide solutions for sustainable domestic resource mobilization for HIV/TB/malaria.¹

What has the pilot leveraged?

The scale of the Global Fund's Pooled Procurement Mechanism (PPM)/wambo.org and the value for money it offers.

- a. Competitive tendering processes and leveraging pooled volumes \rightarrow Favorable terms and conditions
- b. Wambo.org = a digital online procurement platform, with Global Fund grantfunded transactions in 2021 of USD 2.2 billion
- c. Includes several pooled procurement channels (e.g., Global Fund, UNICEF, UNFPA, UNOPS and procurement services agents)

How has the pilot progressed?

- 1. At SC18, an increase was approved for the cap on the pilot to USD 100 million for transactions since November 2019. Against this cap, USD 58 million in orders have been delivered or are in progress.
- 2. As of 31 July 2022, this brings the pilot cumulative total to 150 orders valued at USD 65 million by 35 organizations across 25 countries.
- 3. Domestically financed orders account for 78% of total order value. Unitaid-funded orders comprised 21% of cumulative orders.
- 4. Close to 75% of pilot buyers have placed repeat orders.

Today

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<u>May 2017</u>	<u>Jan. 2018</u>	<u>Mar. 2019</u>	<u>Nov. 2019</u>	<u>Jan. 2020</u>	<u>Mar. 2020</u>	Oct. 2020	<u>Q2 2021</u>	Aug 2021-Jan 2022	<u>Feb. 2022</u>	<u>Mar. 2022</u>	Apr-Sept.	<u>Oct. 2022</u>	Nov. 2022	Ľ
Board	First pilot	SC	Board	Multi-stake-	Key	SC decision on	SC/TERG	Implementation of	USD 50	TERG	<u>2022</u>	Strategy	Board to	
authorizes	transaction	authorizes	authorizes	holder	outcomes	metrics and	exchanges	pilot evaluation	million cap	evaluation	Secretariat to	Committee	make a	
10 pilot		50 additional	up to USD 50m	consultation	from	evaluation	on TORs		reached	(GF/SC18/09)	develop a	to make	decision	
transactions		transactions	in transactions	(See	consultation	criteria for the	for pilot			Request to	proposal for	recommend	-	1
by current PRs		by current	for governments/	GF/SC12/06)	reported to	pilot	evaluation			increase	advancement	ation to the		
using domestic		PRs	NGOs in GF-		Strategy	(GF/SC14/DP04)				financial	of non-Global	Board		
funding		(GF/SC09/DP01)	eligible and		Committee					cap on pilot	Fund-financed			
(GF/B37/DP09)			transitioned		(GF/SC12/06)					(GF/SC18/10)	procurement			
			countries								through PPM/			
			(GF/B42/DP05)					O Strategy Committee	e/Board		wambo.org		29	
¹ The Seventh Replen	nishment Inves	tment Case includ	ed a projection of USD	58.6 billion in dome	 Pilot implementatio 		ariat	-		20				

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and malaria where the Global Fund invests, against even greater needs.

Strategy Committee proposes continuation with non-grant mechanism*

Alongside maintaining access to long-term agreements with suppliers and work with regional procurement platforms to enhance access

Parameters of non-Global Fund-financed procurement channel

Continue the non-grant financed procurement channel through wambo.org with no change to eligible buyers and products:

Eligible buyers: Governments and non-government development organizations in Global Fund-eligible and transitioned countries.

Eligible products: All products, services and functionalities as they become available on wambo.org subject, if applicable, to agreement by the product catalogue owners.

2 **No cap** on transactions (USD value).

- 3 No expansion of product catalogue to NCDs, given mandate and policy considerations as well as lack of current and anticipated future volume leverage to offer value for money beyond existing mechanisms.
- 4 Board reporting through annual NextGen Market Shaping updates.
- 5 Leverage ongoing discussions with partners and regional platforms for potential solutions to pre-financing challenges, noting these are policy driven.

Budgetary implications: estimated incremental operating costs USD 350,000 per year for information technology and staff for operationalization and differentiated monitoring and reporting.

*See <u>GF/B48/05</u> for the full decision paper, which builds on the TERG recommendations.

For Decision: Non-Global Fund-financed procurement mechanism [3/6]

Why is the non-Global Fund-financed procurement mechanism needed and what are the key benefits

Lessons learned from COVID-19 and ongoing global challenges reinforce the need for countries to have options for accessing quality-assured health products efficiently and reliably.

Key benefit \rightarrow An additional tool for achieving Needs to be addressed equitable access A Countries have an additional tool to access favorable terms and conditions for quality assured health products secured through the Global Reliable supply of quality assured health Fund's Pooled Procurement Mechanism when using non-Global Fund products that are available and affordable financing (at the lowest sustainable prices) for programs to diagnose, treat and prevent the three diseases B Improved access to a blend of effective, well-managed and well-networked national, regional and global platforms to address the varying characteristics and needs that may be related to i. specific country characteristics Value for money on health product investments, 2 (e.g., a small market with no supplier interest) or whether via Global Fund grants or other funding ii. specific product characteristics (e.g., small volumes even when pooled at the global level). Approaches to facilitate continued availability Countries can better optimize program implementation and market shaping 3 of health products when transitioning from objectives partner funding, such as Unitaid funding for

Countries can experience better continuity of supply even when changing between funding sources for innovative products

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funding for scale up

innovative products, to Global Fund grant

Alternative Options Considered

	Options	Reasons not recommended
Alternative Option 1	Discontinuing the non-Global Fund-financed procurement mechanism at the end of the pilot in November 2022	 Goes against TERG findings, conclusions and recommendations Risk of reduced access for buyers who have chosen to opt in
Alternative Option 2	Expanding the product catalogue to include Non- Communicable Diseases products	 Not currently within scope or considered appropriate given: 1 Lack of current and anticipated future volume leverage to offer value for money beyond existing mechanisms 2 Significant workload and coordination with new partners required 3 Expansion beyond currently understood mandate

Potential consequences of a delay or rejection of the decision point

- Removes one tool currently available to countries to support achieving value for money for domestic investments to fight the three diseases.
- Ountries have fewer options to access quality-assured health products, which could impact decisionmaking at country level, including for funding request development for the 2023-2025 period or any emergency needs.
- Prevents the opportunity for simplifying the procurement of health products to be scaled through a single channel that can accommodate the transition from Unitaid-funded to Global Fund-funded procurement.
- Without this, the Secretariat's work to scale and advance on capacity building with regional and national procurement channels would be hampered.

Next steps

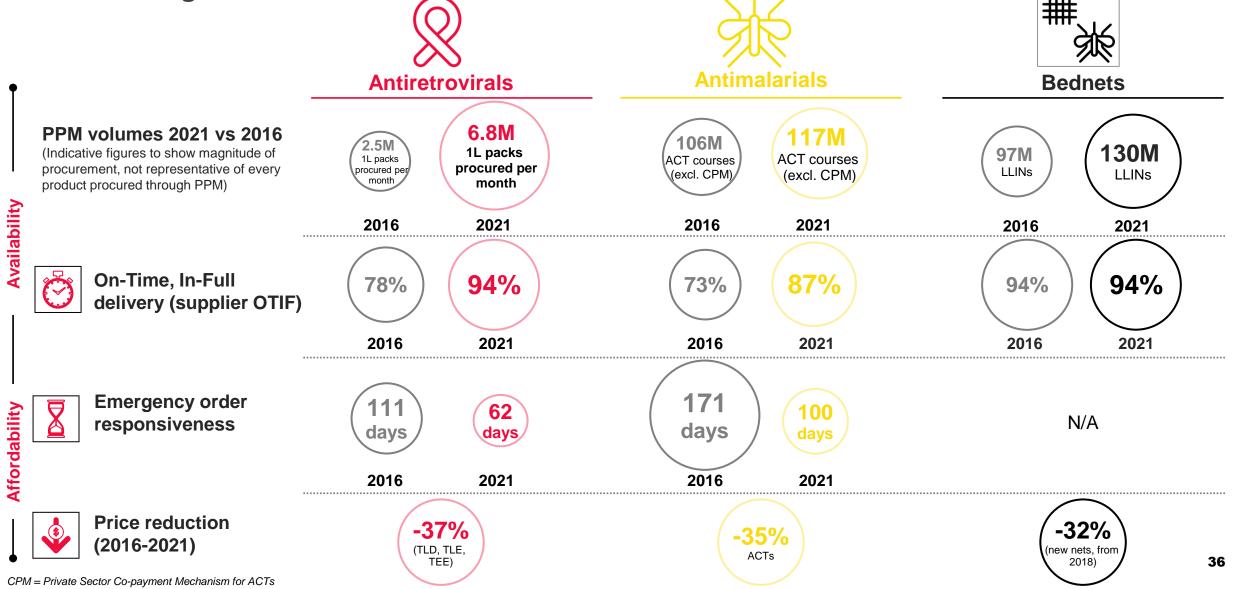
1 The Board will make a decision on the non-grant procurement mechanism.

2 Pending the Board decision, the Secretariat will implement accordingly.

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Strategic achievements for PPM to date

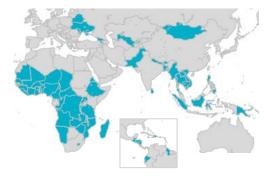
We continue to make strong progress on key metrics including in 2021, despite global supply chain challenges.



PPM procurement / wambo.org dashboard

More than 5,000 shipments of needed health products delivered in 2021, despite international freight and logistics challenges.

Connects 2,170 users from 181 organizations in 93 countries (and PSAs, LFAs, Global Fund)



when compared to 2020

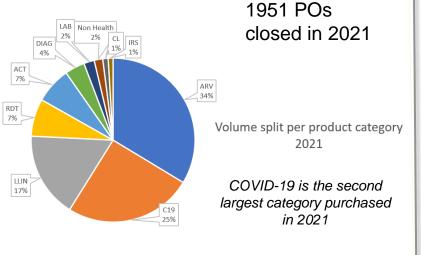
Processed 11'574 invoices for direct payment worth \$1'603M

Procurement services agents/UN-partners:

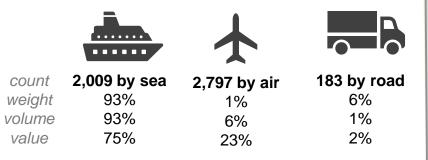
i+ Solutions	IDA Foundation	UNOPS
UNFPA	PFSCM	UNICEF

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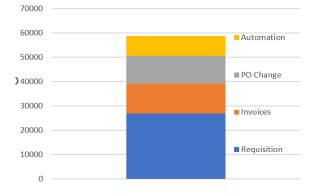


Tracked more than 5,000 shipments* from shipping to delivery



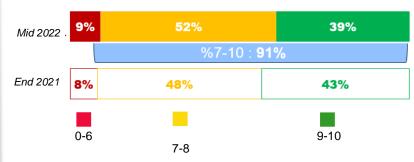
*Based on Advance Shipments Notices received via Wambo * Not displaying other shipping modes (Rail, Others)

Facilitated 58,700 approvals recorded in the system



+23,500 approvals when compared to 2020

Overall user satisfaction with the platform: 91%



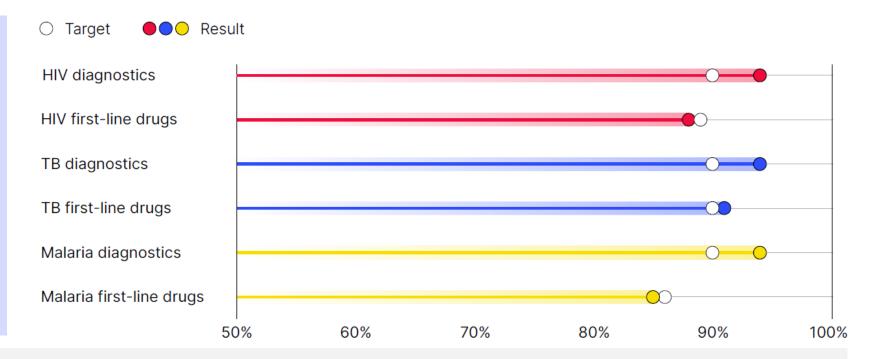
Scale: 0 = Not satisfied at all to 10 = Fully satisfied

37

On Shelf-Availability (OSA) targets were nearly met or exceeded

Product availability at the facility level for service delivery and programmatic impact

- 1. For the six product categories, product availability at the heath facility level was close to or exceeded the target that had been set.
- 2. Continued focus on supply chain strengthening to ensure sustained results.
- Cohort has been expanded to 45 countries to be reported quarterly through spot checks.



Notes:

- 1. Results reported at the end of 2021.
- On-shelf availability is measured as the percentage of health facilities visited providing tracer medicines available on the day of the visit or as per Logistics Management Information Systems status, or as the percentage of health facilities visited providing diagnostic services with tracer items on the day of the visit.
- 3. Countries included in the initiative are Bangladesh, Burkina Faso, Côte d'Ivoire, Congo (Democratic Republic), Ethiopia, Ghana, Haiti, India, Liberia, Malawi, Niger, Nigeria, South Africa, Pakistan, Tanzania (United Republic) and Uganda.
- 4. The Supply Chain Transformation Initiative strengthens in-country supply chains through renewed strategic efforts that enhance and promote advances in the supply of medicines and other key health products to improve universal access.

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Ongoing progress from the PSM Transformation Strategic Initiative 2021-2023

Focus areas

- People-centric supply chain design
- · Efficient data driven supply chain operations
- Improved workforce and stakeholder capacity to govern SCs
- Increased engagement of private sector

\$28Mn Total Allotment

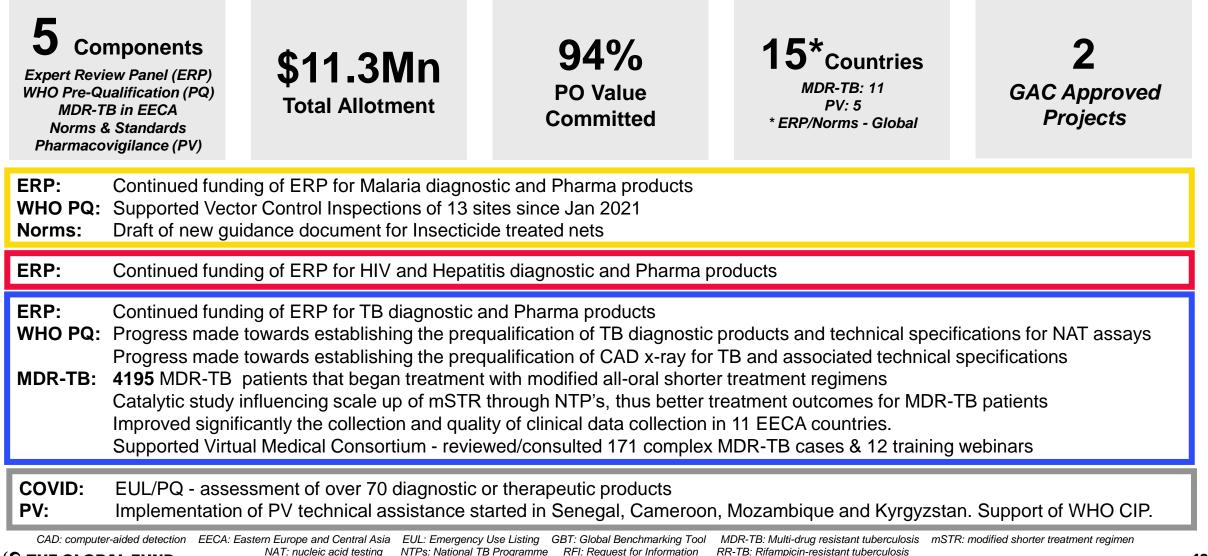
Countries (13 new countries covered through additional funding)

35

62 GAC Approved Projects

- The current PSM Transformation SI has committed 67%* of the allocated funding and seen increased demand from 16 countries to 35
- We have expanded the measurement to 45 countries and four performance metrics and will be sharing data on performance throughout the course of the implementation cycle.
- Some key interventions in the current cycle include
 - Strengthening of HIV forecasting capacity in across a number of countries to help achieve supply chain sustainability and resilience in countries to reduce dependencies on donor funds
 - Improving equity, expanding access to treatment and diagnostics for malaria products by strengthening the capacity and performance of community health workers and working with the private sector to support distribution
 - Working on improving the quality of TB health product management by strengthening warehousing in Bangladesh and Pakistan as a means of intensifying efforts to improve access to quality diagnostics and treatment products

Ongoing progress from the Pre-Qualification and Quality Assurance Strengthening Strategic Initiative 2021-2023



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Annex 2: TERG recommendations

The TERG recommends that the use of wambo.org through domestic funding/non-grant channel should continue beyond its pilot phase to full implementation.*

Strategic Recommendations

- Redesign, enhance and fully implement wambo.org's non-grant channel (NGC)
- Explore the possibility of expanding wambo.org's product catalogue to include NCDs and other disease areas that impact HTM programs
- Help support sustainability by establishing and communicating an operational framework for the use of wambo.org non-grant channel for countries transitioning or projected to transition.

Operational Recommendations

- Design and implement a revised pre-payment mechanism to address regulatory barriers and get wider acceptance from the countries to use wambo.org with domestic funding.
- Explore how wambo.org can be complemented with capacity building
- Explore options to bring more visibility to the wambo.org competitive tendering process
- Promote transparency and in-country data sharing

*See <u>TERG Position Paper on wambo.org pilot Evaluation, GF/SC18/09A (March, April 2022)</u>

Annex 4: Relevant Past Board and Committee Decisions

Relevant Past Decision Point	Summary and Impact
<u>GF/SC20/DP03: Advancement of</u> <u>Non-Global Fund-Financed</u> <u>Procurement Utilizing the Pooled</u> <u>Procurement Mechanism and</u> <u>wambo.org</u> (October 2022)	The Strategy Committee discussed the proposal by the Secretariat to continue the non-Global Fund-financed procurement mechanism, with the same eligible buyers and eligible products as per prior Board decisions, at the conclusion of the pilot, building on findings from an independent evaluation. The Secretariat's proposal included no cap, in line with the TERG's recommendation. The Secretariat shared that it is leveraging ongoing discussions with partners and regional platforms for potential solutions to pre-financing challenges while in parallel working to strengthen the capacities of regional and national procurement channels to ensure value for money and options for access to quality-assured heath products for countries. The Strategy Committee unanimously recommended the Decision Point presented in GF/SC20/DP03 to the Board for approval.
<u>GF/SC18/DP03: wambo.org pilot:</u> <u>Increase to financial cap for non-</u> <u>Global Fund-financed orders</u> (March/April 2022)	Recalling its delegated authority under GF/B42/DP05, the Strategy Committee approved a USD50 million increase to the cap for transactions within the scope of and from the date of the prior decision (GF/B42/DP05). This adjusted the cap for wambo.org pilot transactions to USD 100 million since November 2019.
GF/B44/EDP24: Second extension of the timeline for including COVID-19 products in the wambo.org pilot (April 2021)	Based on the recommendation of the Strategy Committee (GF/SC15/DP01), the Board approved the change in the end date of such period through which non-Global Fund financed transactions for COVID-19 products may be issued as purchase orders by wambo.org until November 2022 or until the Board approves a future strategy for wambo.org if earlier and confirms that all other conditions and flexibilities set forth in GF/B43/EDP07 shall continue to apply.
<u>GF/B43/EDP17: Decision on</u> <u>extending the timeline for</u> <u>including COVID-19 products in</u> <u>the wambo.org pilot</u> (October 2020)	Based on the recommendation of the Strategy Committee (GF/SC14/DP05), the Board approved the extension of the timeline during which non-Global Fund financed transactions for COVID-19 products may be issued as purchase orders to 31 May 2021 and confirmed that all other conditions and flexibilities in GF/B43/EDP07 continue to apply.

[1/6]

Relevant Past Decision Point	Summary and Impact
<u>GF/SC14/13: Extending the</u> <u>timeline for including COVID-19</u> <u>products in the wambo.org pilot</u> (October 2020)	The Strategy Committee discussed the proposal by the Secretariat to extend the timeline for including COVID-19 products in the wambo.org pilot to 31 May 2021. The Strategy Committee recommended the Decision Point presented in GF/SC14/EDP05 to the Board for approval.
<u>GF/SC14/12: wambo.org pilot</u> <u>reporting metrics</u> (October 2020)	The Strategy Committee discussed the proposal by the Secretariat for reporting metrics to monitor progress of the wambo.org pilot for non-grant-financed orders until the end of 2022 or until the Board approves a future strategy for wambo.org. The reporting metrics were based on the results of the January 2020 wambo.org multi-stakeholder consultations with constituencies. The Strategy Committee approved the Decision Point presented in GF/SC14/EDP04. The Secretariat was requested to engage with the TERG for feedback on the reporting metrics (e.g., to identify any key gaps) and to advance next steps related to the planned independent evaluation of the pilot.
<u>GF/B43/EDP07: Extending the</u> wambo.org pilot to include <u>COVID-19 products</u> (July 2020)	The Board extended the scope of the wambo.org pilot to include the purchase of all COVID-19 products available in wambo.org for procurement by Global Fund Principal Recipients. The transactions are subject to agreement by the Global Fund and, if applicable, to agreement by the product catalogue owners or manufacturers, they do not count towards the cap of USD 50 million of transactions for the pilot applicable to non-COVID-19 products, and they may be issued as Purchase Orders by 31 December 2020, unless extended by the Board following recommendation by the Strategy Committee.
	The Board further decided that the transactions for COVID-19 products will be included in the biannual reporting on the Pilot to the Strategy Committee, using metrics for reporting to be agreed by the Strategy Committee in October 2020. However, <u>COVID-19 product transactions will be disaggregated from reporting on other Pilot transactions, so as to enable integration with overall reporting on the COVID-19 response, and to avoid distorting reporting on the original Pilot.</u>

[2/6]

Relevant Past Decision Point	Summary and Impact
GF/B42/DP05: Evolving the wambo.org pilot for non-Global Fund-financed orders (November 2019)	Based on the recommendation of the Strategy Committee (presented in GF/B42/04- Revision 1) the Board decided that, within defined scope of the wambo.org pilot, wambo.org may be made available for non-Global Fund-financed orders by governments and non-government development organizations in Global Fund-eligible and transitioned countries, for all products, services and functionalities as they become available on wambo.org, up to a cap of USD 50 million of transactions; and instructed the Secretariat to undertake consultations early in 2020, an evaluation of the wambo.org pilot in 2022 and bi-annual reporting on progress of the wambo.org pilot to the Strategy Committee. The Board also delegated to the Strategy Committee the authority to: (i) approve a higher cap for transactions within the scope prior to the consultations in 2020; and (ii) establish the future parameters of the wambo.org pilot within the scope, based on the outcome of the 2020 consultations. The Board further requested the Secretariat to include the results of the 2022 evaluation in the development of a strategy for future advancement of wambo.org to be presented for Board approval at the conclusion of the wambo.org pilot no later than November 2022.
GF/SC11/07: Extending access to wambo.org for non-Global Fund- financed orders (October 2019)	The Strategy Committee discussed the proposal by the Secretariat to make wambo.org available for non-grant orders outside of pilot mode. The Strategy Committee requested additional consultations and a formal evaluation of wambo.org prior to exiting the wambo.org pilot. The Strategy Committee unanimously agreed to recommend to the Board for approval making wambo.org available for orders financed with non-grant funds on an evolved pilot basis, whereby governments and non-government development organizations in Global Fund eligible and transitioned countries may have access to wambo.org, to all products, services and functionalities as they become available on wambo.org, subject, if applicable, to agreement by the product catalogue owner, up to a limit of US \$50 million in transaction value. The Strategy Committee would have delegated authority to adjust the value or the nature of the cap.

Relevant Past Decision Point	Summary and Impact
GF/SC09/DP1: wambo.org: Update on Implementation and Request for Additional Domestic Funding Transactions (March 2019)	The Strategy Committee discussed the implementation of wambo.org for Principal Recipients using wambo.org to procure with grant funds, as well as with domestic funds as part of the pilot approved by the Board under GF/B37/DP09. In accordance with delegated authority under GF/B37/DP09, it decided to approve 50 additional transactions to be conducted on wambo.org with domestic funding, on a pilot basis, within the same scope as approved by the Board under GF/B37/DP09. The Strategy Committee further requested the Secretariat to report back to the Strategy Committee with a final evaluation of the pilot and a strategy for future advancement of wambo.org.
GF/B37/DP09: wambo.org: Progress Update and Steps for Advancement (May 2017)	 Based on the recommendation of the Strategy Committee, the Board approved the piloting of a limited number of transactions (no more than ten) by current Principal Recipients using domestic funding via wambo.org. The Board also requested the Secretariat to provide draft indicators of success of the pilot, and to report regularly on the operationalization of the pilot, to the Strategy Committee. Lastly, the Board delegated to the Strategy Committee the authority to approve further domestic funding transactions via wambo.org on a pilot basis.
GF/SC03/DP02: wambo.org: Progress Update and Steps for Advancement (March 2017)	The Strategy Committee discussed and provided input into the progress of wambo.org to date and the supplemental information addressing questions and concerns raised during the voting process and subsequent consultations after the Board did not adopt the same pilot that is presented in GF/SC03/16. The Strategy Committee recommended the Decision Point presented in GF/SC03/16 to the Board for approval with 9 votes in favor, and 1 abstention.

[4/6]

Relevant Past Decision Point	Summary and Impact
GF/AFC02/DP01 and GF/SC02/DP01: wambo.org: Progress Update and Steps for Advancement (October 2016)	The Audit and Finance Committee and the Strategy Committee jointly discussed and provided input into the progress of wambo.org to date and the steps for advancement as described in GF/AFC02/23a and GF/SC02/06a. The Audit and Finance Committee and the Strategy Committee unanimously recommended the decision point therein to the Board for approval. Following the Audit and Finance Committee and the Strategy Committee discussions, the proposed pilot was submitted to the Board in November 2016 as an electronic decision point. The recommendation received the two-thirds majority required for the decision point to pass in the implementer group. However, it did not receive the same required two-thirds majority in the donor group, where two constituencies voted against the decision point and two abstained. As such, the decision point did not pass at that time.
<u>GF/B35/DP08:</u> <u>Sustainability,</u> <u>Transition and Co-</u> <u>financing Policy</u> (April 2016)	Based on the recommendation of the Strategy, Investment and Impact Committee, the Board approves the Sustainability, Transition and Co- Financing Policy, as set forth in Annex 1 to GF/B35/04 - Revision 1.
GF/B34/DP08: Approval of the Amended and Restated Market Shaping Strategy (November 2015)	Based on the recommendation of the Strategy, Investment and Impact Committee, the Board approved the Amended and Restated Market Shaping Strategy, as set forth in Annex 1 to GF/B34/17 - Revision 1 (the "Amended and Restated Market Shaping Strategy"). This decision point and the Amended and Restated Market Shaping Strategy supersede Board decision point GF/B23/DP21 and the previous Market Shaping Strategy set forth in Annex 1 to GF/B23/09 – Revision 1. wambo.org was recognized in the Market Shaping Strategy as one way to channel the Market Shaping Strategy while contributing to its objectives.

Relevant Past Decision Point	[6/6] Summary and Impact
GF/B23/DP21: Global Fund Market Shaping Strategy and Market Shaping Interventions for ARVs (May 2011)	The Board acknowledged the Global Fund's critical role in shaping markets to maximize global access to health products and further emphasized its desire for the Global Fund to more actively shape markets for health products to optimize price, quality, design and sustainable supply. The Board approved the market-shaping strategy recommended by the Market Dynamics Committee, including a set of specific interventions for anti-retroviral medicines (ARVs). This strategy superseded the Market Shaping Strategy approved in 2007 (GF/B15/DP15).
<u>GF/B23/DP09: Plan for</u> <u>Comprehensive Reform:</u> <u>Value for Money</u> (May 2011)	The Board recognized that the Global Fund is well positioned to drive value for money and leverage its role as the primary financier of essential health products to improve quality, price, design, and sustainable supply. The Board asked the Market Dynamics Committee to propose expanded uses of the Global Fund's market dynamics "toolkit". Among other directives, it also requested the Secretariat to take all necessary and appropriate measures to fully implement voluntary pooled procurement and aggressively execute the Market Dynamics Committee recommendations.
GF/B15/DP15: Market Dynamics and Voluntary Pooled Procurement (April 2007)	The Board adopted the objective and guiding principles for market shaping set out at the 14th Board meeting and amended at this meeting. In addition, the Board decided to pursue voluntary pooled procurement as the first element of its market dynamics strategy. As such, the Board required that the pooled service shall be operated by one or more global or regional procurement agent(s), and that the Secretariat "shall direct the Procurement Agent to seek to award contracts for a given product to several suppliers, where possible and appropriate in view of consideration of market dynamics." Finally, participants in the pooled service must agree to direct payment to the procurement agent for purchases. It also determined to strengthen the "Price Reporting Mechanism" (now the Price Quality Reporting Mechanism) and enter into contracts to provide procurement capacity-building services to Principal Recipients.

Annex 5: Relevant Past Documents and Reference Materials

- a) Second Extension of the Timeline for Including COVID-19 Products in the wambo.org Pilot, GF/B44/EDP24 (April 2021)
- b) Extending the Timeline for the Inclusion of COVID-19 Products in the wambo.org Pilot, GF/B43/EDP17 (October 2020)
- c) Extending the wambo.org Pilot to Include COVID-19 Products, GF/B43/EDP07 (July 2020)
- d) Evolving the wambo.org Pilot for Non-Global Fund-financed Orders Revision 1, GF/B42/04 (November 2019)
- e) <u>wambo.org</u>: Progress Update and Steps for Advancement, GF/B37/07 Revision 2 (May 2017)
- f) wambo.org: Progress Update and Steps for Advancement, GF/B35/ER17 (November 2016)